UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA; and THE STATES OF CALIFORNIA, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MICHIGAN, NEVADA, NEW HAMPSHIRE, NEW MEXICO, NEW YORK, TENNESSEE, and TEXAS; THE COMMONWEALTHS OF MASSACHUSETTS and VIRGINIA; and THE DISTRICT OF COLUMBIA; *ex rel.* KASSIE WESTMORELAND, Plaintiffs, v. AMGEN INC.; INTERNATIONAL NEPHROLOGY NETWORK renamed INTEGRATED NEPHROLOGY NETWORK, a d/b/a of DIALYSIS PURCHASING ALLIANCE, INC.; AMERISOURCEBERGEN SPECIALTY GROUP; ASD HEALTHCARE; and AMERISOURCEBERGEN CORPORATION, Defendants.	**CIVIL ACTION NO.** **06-10972-WGY** **JURY TRIAL DEMANDED**

RELATOR'S FOURTH AMENDED COMPLAINT

NATURE OF THE ACTION

1. This is an action brought on behalf of the United States of America by Plaintiff Kassie Westmoreland (hereafter referred to as "Relator") against Defendants pursuant to the *Qui Tam* provisions of the Civil False Claims Act, 31 U.S.C. §§ 3729-33 ("FCA"), referred to herein as the "*Qui Tam* Action." Pursuant to 31 U.S.C. § 3730(b)(2), this *Qui Tam* Action was brought

in camera and under seal.[1] Relator also continues to pursue on her own behalf her claims that Defendant Amgen retaliated against her in violation of the anti-retaliation provisions of the False Claims Act, 31 U.S.C. § 3730(h) and California law. Those claims have been severed to be adjudicated pursuant to arbitration following disposition of the *Qui Tam* action, at the request of Defendant Amgen.

2. The Relator in this case is a former employee of Defendant Amgen. The allegations of this Complaint arise from the Relator's first-hand knowledge of the unlawful practices of the Defendants with respect to the drug Aranesp® (darbepoetin alfa) (hereafter "Aranesp").[2]

3. As more fully described below, Aranesp is an injectable prescription drug developed and manufactured by Defendant Amgen, which was marketed by all Defendants. Aranesp is approved by the FDA to treat anemia in certain patients – specifically anemia related to the treatment of certain nephrology (kidney) and oncology (cancer) patients.

4. Aranesp is administered to patients in many different inpatient and outpatient settings, including physicians' offices, outpatient clinics, hospitals, and dialysis clinics. Additionally, Aranesp is prescribed to patients for self-injection.

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[1] This action previously included several named Plaintiff States that had intervened in this action by filing their own Multi-State Complaint in Intervention (and amendments thereto). This *Qui Tam* action also included claims brought by Relator on behalf of two states, Georgia and New Mexico, that had not intervened. (Collectively, the claims of States are the "State *Qui Tam* Claims.") Based on this Court's ruling that the State *Qui Tam* claims would be dismissed on various grounds, the Plaintiff States and Relator (for claims respecting Georgia and New Mexico) plan to seek appeal of that part of the Court's ruling. The State *Qui Tam* Claims therefore are not repleaded in this Amended Complaint.

[2] This action originally included as Defendants AmerisourceBergen Corporation and AmerisourceBergen Specialty Group. The Court dismissed those Defendants. Relator does not replead herein with respect to those Defendants, but reserves the right to appeal the Court's dismissal of them from her action.

5. At all times relevant to this case, Aranesp was marketed to medical providers by Defendant Amgen with assistance from Defendant International Nephrology Network renamed Integrated Nephrology Network, a d/b/a of Dialysis Purchasing Alliance, Inc. (hereafter "INN"), a purported group purchasing organization ("GPO") that is a subsidiary of Defendant ASD Healthcare, a distributor who is related to AmerisourceBergen Corporation ("ABC") and AmerisourceBergen Specialty Group ("ABSG").

6. Aranesp is usually purchased directly or indirectly by a medical provider from an entity such as Defendant ASD Healthcare. The medical provider thereafter may seek reimbursement for the drug, often by submission of a claim to federal and state governmental health insurance programs, such as Medicare and Medicaid.

7. As a direct, proximate and foreseeable result of Defendants' fraudulent course of conduct set forth herein and conducted on a national scale, Defendants knowingly caused the submission of thousands of false or fraudulent statements, certifications, and claims to government health insurance programs for the reimbursement of the drug Aranesp from at least September 2002 through at least mid-March 2005, when Relator was actively employed by Defendant Amgen.

8. Moreover, the practices complained of herein are continuing. As detailed below, the Defendants' actions and omissions have caused many years of improper and illegal billings to the United States. For the years 2001-2008, Amgen's aggregate United States revenues from Aranesp total over $11 billion, with approximately $6 billion coming from federal and state health care programs such as Medicare and Medicaid.

9. Defendants' fraudulent conduct has had a dramatic impact on Medicare and the government fisc. Spending for epoetin therapy (of which Aranesp is one) is now the single

largest Medicare drug expenditure ($1.75 billion in 2005) and is the second-largest source of dialysis facility income (approximately 22 percent). Department of Health and Human Services, Office of Inspector General, "Medicare Reimbursement for Existing End-Stage Renal Disease Drugs," OEI-03-04-00120 (Washington: DHHS, OIG, May 2004).

10. By their actions, the Defendants have violated several laws, including without limitation, the FCA and the Medicare and Medicaid Patient Protection Act (also known as the Anti-Kickback Statute).

11. The purpose of these unlawful activities was to encourage sales of, and to gain market share for, Aranesp over its competitor drug Procrit® (marketed by Johnson & Johnson) (hereafter "Procrit"), and to switch patients from Procrit and/or the drug Epogen® (hereafter "Epogen" also manufactured by Defendant Amgen) to Aranesp.

12. Among other misconduct, Defendants conspired to encourage medical providers to purchase Aranesp based on representations of the profits that the providers could realize from submission of inflated Aranesp-related claims to Medicare. Defendants encouraged medical providers to overstate the amount of Aranesp administered so that the provider could achieve greater amounts of reimbursement from Medicare and/or Medicaid, thereby making Aranesp more attractive than competitive drugs.

13. As is explained by way of example in this Complaint, Defendants' actions involved, among others, concerted efforts to encourage medical providers throughout the United States to (a) base their clinical decisions on misinformation, such as Defendants' presentation of the purported overfill of Aranesp versus its competitors and/or "special" incentives offered to Aranesp purchasers who contracted with INN, (b) to overdose patients with Aranesp overfill, that was, in some cases, prescribed by the physician and, in any event, medically unnecessary;

and (c) to submit overstated claims relating to Aranesp overfill that was not administered to patients.

14. This misconduct was based on collusion and conspiracy among the Defendants to target medical providers who could provide lucrative business for Defendants through the purchase of Aranesp, as well as medical providers who could influence other providers to contract with Defendants for Aranesp.

15. In addition to causing damage to programs such as Medicare, Defendants' actions have also put patient safety and health at risk. The population of patients for whom Aranesp is indicated is especially vulnerable. Though Amgen was aware of issues earlier, beginning on or about March 9, 2007, the FDA issued a series of black box warnings for Aranesp when used in kidney and cancer patients, the most serious warning available on a drug's label. The black box warned of increased risk of death, of serious cardiovascular or thromboembolic events, and more rapid tumor progressions. The new warnings cautioned physicians to administer the *lowest dose possible* in order to bring red blood cell counts to the lowest level necessary to avoid blood transfusions.

16. Concerns that, rather than helping patients, Aranesp can increase the risk of tumor growth and shorten survival in patients with cancer, and increase the risk of heart attack, heart failure, stroke, and blood clots in other patients, led the FDA to impose a Risk Evaluation and Mitigation Strategy on Amgen for Aranesp in February 2010.

17. One of Amgen's responses to the black box warnings appears to have been to treat them as humorous. A script for a July 2007 meeting of Amgen's Nephrology Business Unit from the files of Amgen Vice President of Sales Leslie Mirani included a joke about "black box

warnings," following up on the FDA's February 2007 warning about potential harm from Aranesp.

Two recent studies provide further evidence of harm or potential harm:

(a) A study published online on October 30, 2009 by the New England Journal of Medicine, raised fresh safety concerns with Aranesp. The study led by Dr. Marc Pfeffer, a heart specialist at Brigham and Women's Hospital in Boston, involved 4,038 patients with Type 2 diabetes, kidney problems and moderate anemia. As of that date, it was the largest ever study of any ESA drug and the first to compare Aranesp to placebo. The study examined the use of Aranesp in the prevention of heart attacks, heart failure, strokes or the need for dialysis. The study found that not only was Aranesp ineffective in these applications, Aranesp nearly doubled the risk of stroke in people with diabetes and chronic kidney problems who are not yet sick enough to need dialysis; and

(b) A second study, published on November 10, 2009 in the Journal of the National Cancer Institute, was led by Dr. Dawn Hershman of New York-Presbyterian Hospital/Columbia University. That study tracked the use of ESAs such as Aranesp in more than 55,000 cancer patients over a decade. The study found the use of ESAs more than doubled the patient's risk of developing blood clots in the lungs or legs while not reducing the need for blood transfusions (the original purpose of ESAs when first approved in 1989).

18. Information about Defendants' illegal conduct is detailed further in the paragraphs below.

JURISDICTION AND VENUE

19. This Court has jurisdiction over this action under the False Claims Act ("FCA") causes of action pursuant to 28 U.S.C. §§ 1331, 1345, and 31 U.S.C. §§ 3732(a), 3730.

20. Venue is appropriate as to the Defendants in that the Defendants can be found, reside and/or transact business in this judicial district, and/or acts proscribed by 31 U.S.C. § 3729 have been committed by the Defendants in this judicial district. Therefore, venue is proper within the meaning of 28 U.S.C. § 1391(b) and (c), and 31 U.S.C. § 3732(a).

21. The Relator's action is not based upon the disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government [General] Accounting Office report, hearing, audit, or investigation, or from the news media. At the time the original complaint was filed, there was no such disclosure, and in any event, as discussed below, this action is based on Relator's direct and independent knowledge as an employee (now former) of Defendant Amgen, not on any such disclosure. Furthermore, as discussed and demonstrated in Relator's Complaint and amendments and prior proceedings before the Court, Relator is an "original source" of the information upon which her action is based: she has direct and independent knowledge of the information on which the action is based; and she voluntarily provided her information to the government in 2006, before filing her Complaint, and has made several subsequent disclosures prior to amending her Complaint. *See generally* 31 U.S.C. § 3730(e)(4). Her complaint and any amendments were properly served on each sovereign named.

THE PARTIES

22. The real party in interest to the FCA Q*ui Tam* claims herein is the sovereign government of the United States of America. The United States of America has filed with this

Court a Notice of Not Intervening at this Time (but is continuing its investigation and filed a Statement of Interest relating to Defendants' Motion asking the Court to clarify or reconsider its ruling on Count I as to Medicare).

23. Accordingly, at this time, Relator is pursuing her cause of action on behalf of the United States on the FCA *Qui Tam* claims set forth herein. *See, e.g.*, 31 U.S.C. § 3730(c) (3).

24. Relator Kassie Westmoreland is a citizen of the United States of America. She is a resident of California, and a former employee of Defendant Amgen. She brings this *Qui Tam* action based upon direct, independent, and unique information obtained during the period of her active employment at Amgen from September 2002 to mid-March 2005, at which time she went on temporary disability leave as a result of Amgen's unlawful retaliation against her as detailed *infra*.

25. Defendant Amgen Inc. ("Amgen"), a Fortune 500 company, is a publicly-traded diversified, human therapeutics company in the biotechnology industry. It conducts business throughout the United States (including Massachusetts) and in many other countries. Its principal place of business is Thousand Oaks, California. Amgen is traded on the NASDAQ under the symbol "AMGN." Amgen engages in the discovery, development, manufacture, and delivery of biotherapeutics (*e.g.*, prescription drugs) for various medical needs. The company provides products for the treatment of various human ailments, including anemia, arthritis, psoriasis, cancer treatment side effects, and side effects of dialysis. Amgen was the original developer of the drug Aranesp® (darbepoetin alfa) ("Aranesp") approved by the United States Food and Drug Administration in 2001 for the treatment of anemia associated with chronic renal failure (both in patients on dialysis and those not on dialysis) and in 2002 for the treatment of chemotherapy-induced anemia in patients with nonmyeloid malignancies.

26. Defendant International Nephrology Network ("INN") was formed in September 2003 and operated as one of several d/b/as of International Physicians Networks ("IPN") (other d/b/as used by IPN included International Oncology Network and International Rheumatology Network). In 2002, AmerisourceBergen Corporation ("ABC") acquired a 20% ownership interest in IPN; in April 2003, ABC acquired an additional 40% interest in IPN; and in January-April 2004 ABC acquired the final 40% of IPN, thus making IPN a wholly owned subsidiary of ABC. INN operated as a d/b/a of IPN until April 2008, at which time that d/b/a was withdrawn, and INN was renamed Integrated Nephrology Network and was registered as a d/b/a of Dialysis Purchasing Alliance, Inc. In this Complaint, INN shall be referred to as INN regardless of which name it was doing business as or under at what point in time. Since at least 2004, INN has operated as a business unit of ABSG. INN, whose principal place of business is in Frisco, Texas, is purportedly a "group purchasing organization" ("GPO") that focuses on nephrology practices and physicians. Amgen started doing business with INN in 2003. INN does business throughout the United States, including in the Commonwealth of Massachusetts.

27. Defendant ASD Healthcare a/k/a ASD Specialty Healthcare, Inc. ("ASD" or "ASD Healthcare"), is a pharmaceutical distributor operated by ABSG, whose ultimate parent is ABC. Its principal place of business is Frisco, Texas. ASD Healthcare distributes drugs throughout the United States, including the Commonwealth of Massachusetts, and is the preferred distributor for INN.

FEDERAL AND STATE LAWS AND REGULATIONS

A. The Anti-Kickback Laws of the United States and the States

28. The Medicare and Medicaid Patient Protection Act, also known as the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that the

remuneration and gifts given to those who can influence health care decisions corrupts medical decision-making and can result in the provision of goods and services that are more expensive and/or medically unnecessary or even harmful to a vulnerable patient population. To protect the integrity of the federal health care programs, Congress enacted a prohibition against the payment of kickbacks in any form. The Anti-Kickback Statute was enacted in 1972 "to provide penalties for certain practices which have long been regarded by professional organizations as unethical, as well as unlawful . . . and which contribute appreciably to the cost of the Medicare and Medicaid programs." H.R. Rep. No. 92-231, 92d Cong., 1st Sess. 108 (1971), reprinted in 1972 U.S.C.C.A.N. 4989, 5093.

29. In 1977, Congress amended the Anti-Kickback Statute to prohibit receiving or paying "any remuneration" to induce referrals and increased the crime's severity from a misdemeanor to a felony with a penalty of $25,000 and/or five years in jail. *See* Social Security Amendment of 1972, Pub. L. No. 92-603, 241(b) and (c); 42 U.S.C. § 1320a-7b. In doing so, Congress noted that the purpose of the Anti-Kickback Statute was to combat fraud and abuse in medical settings that "cheats taxpayers who must ultimately bear the financial burden of misuse of funds . . . diverts from those most in need, the nation's elderly and poor, scarce program dollars that were intended to provide vitally needed quality health services . . . [and] erodes the financial stability of those state and local governments whose budgets are already overextended and who must commit an ever-increasing portion of their financial resources to fulfill the obligations of their medical assistance programs." H.R. Rep. No. 95-393, pt. 2, at 37, reprinted in 1977 U.S.C.C.A.N. 3039, 3047.[3]

[3] Through the amendments Congress sought to "give a clear, loud signal to the thieves and the crooks and the abusers that we [Congress] mean to call a halt to their exploitation of the public

30. In 1987, Congress again strengthened the Anti-Kickback Statute to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142, Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

31. The Anti-Kickback Statute prohibits any person or entity from knowingly and willfully offering to pay or paying any remuneration to another person to induce that person to purchase, order, or recommend any good or item for which payment may be made in whole or in part by a federal health care program, which includes any State health program or health program funded in part by the federal government. 42 U.S.C. §§ 1320a-7b(b), 1320a-7b(f).

32. The statute provides, in pertinent part:

> (b) Illegal remunerations
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> * * *
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person –
>
> (A) To refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under Federal health care program, or
>
> (B) To purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> Shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

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and the public purse." 123 Cong. Rec. S31767 (daily ed. Sept 30, 1997) (statement of Sen. Talmadge).

42 U.S.C. § 1320a-7b(b).

33. In addition to criminal penalties, a violation of the Anti-Kickback Statute can also subject the perpetrator to exclusion from participation in federal health care programs (42 U.S.C. § 1320a-7(b)(7)), civil monetary penalties of $50,000 per violation (42 U.S.C. § 1320a-7a(a)(7)), and three times the amount of remuneration paid, regardless of whether any part of the remuneration is for a legitimate purpose, 42 U.S.C. § 1320a-7a(a).

34. Concern about improper drug marketing practices prompted the Inspector General of the Department of Health and Human Services the ("HHS OIG") to issue a Special Fraud Alert in 1994 concerning prescription drug marketing practices that violated the Anti-Kickback Statute. *See* Special Fraud Alert: Prescription Drug Marketing Schemes, 59 Fed. Reg. 65,376 (Dec. 29, 1994).

35. In May 2003, the HHS OIG published further guidance on marketing practices which may constitute kickbacks known as the "OIG Compliance Program Guidance for Pharmaceutical Manufacturers," 68 Fed. Reg. 23731 (May 5, 2003) (the "OIG Guidelines"). The Guidelines address, *inter alia*, the conflicts which may arise when a pharmaceutical manufacturer provides educational or research funding to "entities in a position to make or influence referrals." *Id.* As a general rule, educational grants should be made without conditions or restrictions, otherwise the arrangement becomes a forbidden *quid pro quo* relationship:

> Manufacturers should take steps to ensure that neither they, nor their representatives, are using these activities to channel improper remuneration to physicians or others in a position to generate business for the manufacturer or to influence the content of the program.

Id. § II (b)(2).

36. The Anti-Kickback Statute not only prohibits outright bribes and rebate schemes, but also prohibits any payment or other remuneration by a drug company to a physician or other person which has as one of its purposes the inducement of the physician to write prescriptions for the company's pharmaceutical products or the inducement of the physician to influence or recommend the prescribing of the product.

37. Compliance with the Anti-Kickback Statute is a precondition to participation as a health care provider under a Government Health Care Program, including Medicare and the state Medicaid programs. Moreover, compliance with the Anti-Kickback Statute is a *condition of payment* for drug claims administered by physicians for which Medicare or Medicaid reimbursement is sought.

38. Under 42 U.S.C. § 1395y(a)(1)(A), "nonpayment may be made [under the Medicare statute] for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury."

39. The Second Circuit has held that, "[s]ince § 1395y(a)(1)(A) expressly prohibits payment if a provider fails to comply with its terms, defendants' submission of the claim forms implicitly certifies compliance with its provision." *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 701 (2d Cir. 2001).

40. Kickbacks are, by definition, not "reasonable and necessary for the diagnosis or treatment of illness or injury."

41. Federal law makes clear that violation of the Anti-Kickback Statute can support false claims liability.

B. The False Claims Act

42. The FCA, 31 U.S.C. § 3729(a)(1)(A), makes "knowingly" presenting or causing to be presented to the United States any false or fraudulent claim for payment or approval a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty of between $5,500 and $11,000 per claim for claims made on or after September 29, 1999.

43. The FCA, 31 U.S.C. § 3729(a)(1)(B), makes "knowingly" making, using, or causing to be used or made, a false record or statement material to a false or fraudulent claim, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of between $5,500 and $11,000 per claim for claims made on or after September 29, 1999.

44. The FCA, 31 U.S.C. § 3729(a)(1)(C)), makes any person, who conspires to commit a violation of the FCA, liable for three times the amount of the damages the Government sustains and a civil monetary penalty of between $5,500 and $11,000 per claim for claims made on or after September 29, 1999.

45. The FCA defines a "claim" to include any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested. 31 U.S.C. § 3729(b)(2).

46. The FCA, 31 U.S.C. § 3729(b)(1) provides that "(1) the terms 'knowing' and 'knowingly' – (A) mean that a person, with respect to information – (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii)

acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud."

47. The FCA, 31 U.S.C. § 3729(b)(4) provides that "(4) the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."

48. Furthermore, the FCA, 31 U.S.C. § 3730(h), provides relief to employees who have been retaliated against in their employment because of lawful acts done by the employee in furtherance of efforts to stop one or more violations of the FCA. Such retaliation may include discharge, demotion, suspension, threats, harassment or any other type of discrimination in the terms and conditions of employment. The employee is entitled to all relief necessary to make that employee whole, including reinstatement, two times back pay, interest on the back pay, and compensation for any special damages, including litigation costs and reasonable attorney's fees.

C. Group Purchasing Organizations

49. Group purchasing organizations (GPOs) are buying consortiums or associations of hospitals, clinics, doctors, and healthcare organizations that are designed to leverage the aggregate purchasing power of members and thereby increase their ability to negotiate contract terms with various suppliers of drugs, medical devices and other goods and services. GPOs negotiate such acquisitions, but do not typically purchase anything from the suppliers. Once a contract is in place, the member hospitals and healthcare organizations can make purchases under it. *See, e.g.*, Department of Health and Human Services Office of Inspector General ("OIG") Report: "Review of Revenue from Vendors at Three Group Purchasing Organizations and Their Members," (A-05-03-00074) (Jan. 19, 2005).

50. The term "group purchasing organization" is defined at 21 CFR § 203.3 as follows:

> § 203.3 Definitions.
>
> (o) *Group purchasing organization* means any entity established, maintained, and operated for the purchase of prescription drugs for distribution exclusively to its members with such membership consisting solely of hospitals and health care entities bound by written contract with the entity.

GPOs act as agents for their members, but they may be compensated through "administrative" or "service" fees from the vendors or suppliers. These fees are paid by the vendors or suppliers to the GPO in exchange for administrative services and the ability to sell through the GPO to its members. *See* OIG Report, *supra*. Typically, the fees are calculated as a small percentage, generally less than 3%, of the revenue generated under the GPO contract. *Id.*

51. The Anti-Kickback Statute provides certain exemptions (known as "safe harbors") to exclude certain conduct from its ambit, *as long as* the involved parties have complied with all the conditions of the safe harbor. One such safe harbor involves GPO administrative fees.

52. Regulations promulgated by the HHS OIG limit this "safe harbor" by imposing standards for the written agreement between the GPO and its members. *See* 42 C.F.R. § 1001.952(j). A GPO may invoke the "safe harbor" if:

> (1) The GPO's written agreement with each individual or entity purchasing items or services states either (a) that the vendor will pay a fee to the GPO of 3 percent or less of the purchase price of the goods or services provided by the vendor; or (b) the specific amount or, if not known, the maximum amount the GPO will be paid by each vendor expressed either as a fixed sum or a fixed percentage of the value of the purchases by the members of the group;

> and
>
> (2) The GPO must disclose to the entities who are health care providers in writing at least annually the amount received from each vendor with respect to purchases made by or on behalf of the entity.

53. Parties to a GPO arrangement cannot obtain safe harbor protection by entering into a contract that complies with the written agreement requirement of a safe harbor and appears, on paper, to meet all of the other safe harbor requirements, but that does not reflect the actual arrangement between the parties. *See generally* 42 C.F.R. § 414.802 (fees must be "bona fide" to be excluded from Average Sales Price calculations).

54. Administrative or service fees charged by GPOs and paid to them by vendors are also material to Medicare's calculation of the ASP at which a covered drug is reimbursed.

55. Beginning on January 1, 2005, Medicare Part B reimbursement for Aranesp in the physician clinic setting was based on a new formula calculated as "average selling price" ("ASP") plus six percent – *i.e.*, ASP + 6%. The regulations governing ASP were promulgated in 2004. *See* 42 C.F.R. § 414.800. In calculating ASP, a manufacturer such as Amgen must deduct "price concessions," but "*bona fide* service fees" (emphasis added) are not considered a concession. *See* 42 C.F.R. § 414.804(a)(2).

> 'Bona fide service fees' means fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

See 42 C.F.R. § 414.802.

56. When a manufacturer submits its ASP-required information to CMS (which it is required to do on a quarterly basis), the manufacturer's CEO, CFO, or Authorizing Official must certify that "the reported Average Sales Prices were calculated accurately and that all information and statements made in this submission are true, complete, and current to the best of my knowledge and belief and are made in good faith. I understand that the information contained in this submission may be used for Medicare reimbursement purposes." 42 C.F.R. § 414.805 and Form Addendum B.

GOVERNMENT HEALTH INSURANCE PROGRAMS

57. The Health Insurance for the Aged and Disabled Program, popularly known as the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq.*, (hereinafter "Medicare"), is a health insurance program administered by the Government of the United States that is funded by taxpayer revenue. Medicare is overseen by the United States Department of Health and Human Services through its Center for Medicare and Medicaid Services ("CMS").

58. Medicare was designed to be a health insurance program and to provide for the payment of hospital services, medical services and durable medical equipment to persons over sixty-five (65) years of age, and for certain others that qualify under the terms and conditions of the Medicare Program.

59. Payments made under the Medicare Program include payment for certain prescription drugs used during treatment at an appropriate medical facility and otherwise, as well as certain injectable drugs and drugs used in conjunction with the treatment of patients with cancer and chronic kidney disease.

60. Pursuant to the Medicare Prescription Drug Improvement and Modernization Act of 2003, effective January 1, 2006, Medicare Part D took effect, extending prescription drug coverage to all Medicare eligible persons who choose to participate in Part D.

61. Reimbursement for Medicare claims is made by the United States through CMS which contracts with private insurance carriers to administer and pay claims from the Medicare Trust Fund. 42 U.S.C. § 1395u. In this capacity, the carriers act on behalf of CMS.

62. The Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (hereafter "Medicaid"), is a Health Insurance Program administered by the Government of the United States and the various individual States and is funded by State and Federal taxpayer revenue. The Medicaid Program is overseen by the United States Department of Health and Human Services.

63. Medicaid was designed to assist participating states in providing medical services, durable medical equipment and prescription drugs to, among others, financially needy individuals that qualify for Medicaid. The States directly pay providers, with the States obtaining the federal share of the payment from accounts which draw on the United States Treasury. 42 C.F.R. §§ 430.0-430.30 (1994).

64. The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") (now known as "TRICARE"), 10 U.S.C. §§ 1071-1106, provides benefits for health care services furnished by civilian providers, physicians, and suppliers to members of the Uniformed Services and to spouses and children of active duty, retired and deceased members. The program is administered by the Department of Defense and funded by the Federal Government. CHAMPUS pays for, among other items and services, prescription drugs for its beneficiaries.

65. The federal government, through its Departments of Defense and Veterans Affairs, maintains and operates medical facilities including hospitals, and receives and uses federal funds to purchase prescription drugs for patients treated at such facilities and otherwise. In addition, under the Public Health Service Act, the Section 340B Drug Pricing Program, and the Veterans Health Care Act of 1992, the federal government directly or indirectly provides funds to certain other federal agencies and to state and local facilities and programs, including to non-profit disproportionate share hospitals ("DSH"). *See generally* 38 U.S.C. § 8126.

66. The Federal Employees Health Benefits Program ("FEHBP") provides health care benefits for qualified federal employees and their dependents. It pays for, among other items and services, prescription drugs for its beneficiaries. (Together these programs described in paragraphs 57-66, and any other government funded healthcare programs, shall be referred to as "Federal Health Care Programs" or "Government Health Care Programs").

67. Reimbursement practices under all Government Health Care Programs closely align with the rules and regulations governing Medicare reimbursement. The most basic requirement for reimbursement eligibility under Medicare, Medicaid and other Government Health Care Programs is that the service provided must be reasonable and medically necessary. *See*, *e.g.*, 42 U.S.C. § 1395y(a)(1)(A); 42 U.S.C. § 1396, *et seq.*; 42 C.F.R. § 410.50. Medical providers are not permitted to bill the government for medically unnecessary services or procedures performed solely for the profit of the provider. *See id.*

68. Each of the Government Health Care Programs requires every provider who seeks payment from the program to promise and ensure compliance with the provisions of the Anti-Kickback Statute and with other federal laws governing the provision of health care services in

the United States. That agreement represents an ongoing obligation, and the provider must notify the government of any change in information or certifications provided.

69. In other words, if a provider tells CMS or its agent that it provided goods or services in violation of the Anti-Kickback Statute, that were not medically unnecessary, that were performed solely for the profit of the provider, and/or that violated another relevant law, CMS will not pay the claim.

70. CMS will also not pay a claim relating to reimbursement for goods or services that were not actually provided.

71. Physicians and hospitals enter into Provider Agreements with CMS in order to establish their eligibility to seek reimbursement from the Medicare Program. As part of that agreement, without which the hospitals and physicians may not seek reimbursement from Federal Health Care Programs, the provider must sign the following certification:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. The Medicare laws, regulations, and program instructions are available through the [Medicare] contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal Anti-Kickback statute and the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare.

Form CMS-855A (for institutional providers); Form CMS-855I (for physicians and non-physician practitioners), (effective 2001). (Attached as Exhibits I & J)

72. The "Certification Statement" that the medical provider must sign also contains the following provisions and requirements *inter alia*, for "initial *and continuous* enrollment in the Medicare program," and instructs that by signing the Certification Statement, the provider "agree[s] to adhere to all of the requirements listed therein." (Emphasis added.)

73. Further, it states: "You MUST sign and date the certification statement below in order to be enrolled in the Medicare program. In doing so, you are attesting to *meeting and maintaining* the Medicare requirements stated below." (Emphasis added).

74. By signing the "Certification Statement," the provider certifies, *inter alia,* to the following:

> 1. I have read the contents of this application, and the information contained herein is true, correct, and complete. *If I become aware that any information in this application is not true, correct, or complete, I agree to notify the Medicare [program] immediately*.
> . . .
>
> 3. I have read and understand the Penalties for Falsifying Information…I understand that any deliberate omission, misrepresentation, or falsification of any information contained in this application *or contained in any communication supplying information to Medicare* …may be punished by criminal, civil or administrative penalties, including but not limited to the denial or revocation of Medicare billing privileges, and/or imposition of fines, civil damages, and/or imprisonment. (Emphasis added).
> . . .
> 8. I *will not knowingly present or cause to be presented a* false or fraudulent claim for payment by Medicare, and *will not* submit claims with deliberate ignorance or reckless disregard of their truth or falsity. (Emphasis added).

75. The certifications made by the medical provider in the Provider Agreement, which are mandatory for Medicare enrollment, expressly create a continuing duty to comply with the conditions of participation in and payment by the Medicare program. In particular:

(a) Prior to signing the Agreement, the provider is advised of the criminal, civil, and administrative penalties "for deliberately furnishing false information in this application *to gain or maintain enrollment* in the Medicare program." Section 14 (emphasis added); and

(b) Among those penalties are criminal sanctions for fraud, concealment and any trick, scheme or device or scheme to defraud, any false or

fraudulent statement or representation or any false writing or document, violations of the FCA, civil penalties for billing for a medical or other item or services that the provider knows or should know was not provided as claimed. *Id.* "Remedies include compensatory and punitive damages, restitution, and recovery of the amount of the unjust profit." *Id.*

76. When a provider submits a claim for payment, he or she does so subject to and under the terms of its certification to the United States that the services for which payment is sought were delivered in accordance with federal law, to include without limitation the Anti-Kickback Statue.

THE RELATOR

77. Relator Kassie Westmoreland is a registered pharmacist with a Bachelor of Science in Pharmacy and Biology and a Master of Business Administration. She currently lives in California.

78. In September 2002, she took a position with Defendant Amgen as a professional sales representative. At the time, Amgen had its sales and marketing staff organized into separate groups focused on specific drugs or "brands" that Amgen produced. One such drug was Aranesp, and when Relator joined Amgen, she was assigned to be a "Professional Sales Representative" ("PSR") in the Aranesp sales group.

79. Amgen's sales and marketing of Aranesp were coordinated and overseen from Amgen's corporate headquarters in Thousand Oaks, California. Amgen employed numerous PSRs like Relator throughout the United States to market Aranesp, and each PSR had his/her own geographical area and/or physician practice area.

80. Relator was Amgen's Aranesp PSR for the State of Oregon and Southwest Washington. In that capacity she called on nephrology (kidney) practices, hospitals, long term care facilities, and multi-specialty clinics. In her territory, there was another PSR who only called on dialysis centers, and four other Amgen PSRs who marketed Aranesp to oncology practices in the territory as well as a Hospital System Manager who called on nephrology and oncology customers, at teaching institutions including Oregon Health and Science University, and the Portland Veterans Administration Hospital.

81. Although Relator lived in Oregon at that time, she nevertheless had extensive contacts with other Aranesp PSRs from around the country through training seminars and Aranesp sales staff meetings, which included quarterly, semi-annual, and annual meetings. She also had weekly phone contact with other district PSRs and district managers as well as other PSRs around the country. Relator also had extensive contacts with upper-level Aranesp sales managers and directors through these seminars and staff meetings, as well as countless telephone conferences and e-mails.

82. Relator worked as an Aranesp PSR from approximately September 2002 to March 2004. She witnessed firsthand and heard about promotion of "overfill" by Defendant Amgen and medical providers billing for Aranesp "overfill." Defendant Amgen's promotion of "overfill" and billing for "overfill" is discussed more fully below.

83. In March 2004, Relator left the Aranesp sales force and took a promotion to be a product manager for Aranesp in Amgen's home office in Thousand Oaks, California. As a Product Manager for Aranesp, Relator focused more broadly on marketing and advertising of the drug, as opposed to direct sales.

84. As part of Relator's new position in Amgen's marketing department, Relator was assigned responsibility for managing Amgen's relationship with Defendant INN, which Relator had been informed was an independent entity (and qualified as a GPO) that focused on nephrology practices and physicians. Defendant Amgen's relationship with Defendants INN and its related entity ASD Healthcare is discussed more fully below.

85. As detailed below, while in the employ of Defendant Amgen, Relator personally observed Defendants' unlawful practices, and participated in and was privy to meetings, conversations, and other internal communications, including at the management and headquarters levels of the company. Among other things, in the regular course of her employment, Relator had access to e-mail and internal documents and data which describe, document, and reflect the conduct discussed herein. Relator also had many interactions with managers, employees, sales representatives, physicians, hospital representatives, and other third parties relating to Defendants' business practices on a national level.

ANEMIA PRODUCTS MANUFACTURED BY AMGEN

86. Defendant Amgen manufactures three anemia products, as detailed herein: Aranesp; Procrit; and Epogen.

A. Aranesp (Darbepoetin Alfa)

87. Aranesp (darbepoetin alfa) is an injectable prescription drug developed and manufactured by Defendant Amgen that is indicated to treat certain forms of anemia, namely those associated with chronic kidney disease and chemotherapy induced anemia in the treatment of certain nephrology and oncology patients. Patients with kidney disease and/or cancer often have decreased levels of red blood cells, which are essential to transporting oxygen throughout

the body. The absence and/or decreased levels of red blood cells can cause anemia in such patients.

88. Aranesp is an erythropoeisis-stimulating agent (ESA) that purportedly stimulates or boosts the production of red blood cells, with the goal of lowering the risk of anemia.

89. Treatment of anemia is a vital and integral part of the medical care of nephrology and cancer patients, given that anemia can undermine the efficacy of a medical treatment plan, and/or it can lead to severe health consequences for the patient, including death.

90. Aranesp was to be prescribed to increase red blood cell counts, specifically to increase hemoglobin levels, so as to avoid the need for blood transfusions in patients experiencing kidney failure or chemotherapy induced anemia.

91. On or about September 17, 2001, the FDA approved Aranesp for use in the United States for the treatment of anemia associated with chronic renal failure (both in patients on dialysis and those not on dialysis). On or about July 17, 2002, the FDA approved the drug for the treatment of chemotherapy-induced anemia in patients with nonmyeloid malignancies.

92. Safety and efficacy have *not* been established in other conditions and Aranesp is not approved for other uses, or in dosages different from those approved in the label. The dosage of Aranesp varies somewhat according to the patient's weight and condition, but a typical dosage would be 25-40 mcg for a weekly injection, or 60 mcg for an injection every two weeks for pre-dialysis patients.

93. Pharmacists submit claims for Aranesp using the several National Drug Code ("NDC") numbers for Aranesp depending on the dosage; these NDCs are attached in Exhibit A**.** Medical providers who administer Aranesp on an outpatient basis use procedure codes shown on Exhibit A.

94. Since its introduction to the prescription drug marketplace in 2001, United States sales of Aranesp have been substantial. According to Amgen's public filings, aggregate (2001-2008) United States revenues for Aranesp have totaled over $*11 billion* during those years.

95. Moreover, since the drug was first introduced, Aranesp sales in the United States have increased steadily and dramatically year-after-year until the FDA began issuing black box warnings in 2007: from $27 million in its first year, 2001; to $285 million in 2002; to $980 million in 2003; to $1.533 billion in 2004; to $2.104 billion in 2005; to $2.79 billion in 2006; to $2.154 billion in 2007; and $1.65 billion through 2008.

96. Of these revenues, approximately $6 billion is from Government Health Care Programs: over $372 million from Medicaid and at least $5.6 billion from Medicare and other Government Health Insurance Programs.

97. Relator was employed at Amgen during the period of tremendous revenue growth for Aranesp (2002-2006 and before the first black box warning was issued).

98. On or about March 9, 2007, the FDA issued a black box warning for Aranesp, the most serious warning available for a drug's label, warning of increased risk for death, of serious cardiovascular or thromboembolic events, and more rapid tumor progressions. The new warning cautioned physicians to administer *the lowest dose possible* in order to bring red blood cell counts to the lowest level necessary to avoid blood transfusions. The black box warning described the results of six clinical studies which demonstrated that survival was shorter and tumors progressed faster when used to achieve hemoglobin levels of 12 grams per deciliter ("g/dL") of blood or greater in cancer patients.

99. On or about November 8, 2007, the FDA approved revisions to prior black box warnings, which expanded the labeling changes made in March 2007, to provide specific dosing

information. The revised black box warning stated that dosing should be individualized to "achieve and maintain hemoglobin levels within the range of 10 to 12 g/dL." For kidney patients, the revised warning read that: "patients experienced greater risks for death and serious cardiovascular events when administered ESAs to target higher versus lower hemoglobin levels." For cancer patients, the new warnings emphasized that Aranesp could cause tumor growth and shorten survival among patients with advanced breast, head and neck lymphoid tumors, and non-small cell lung tumors.

100. On or about March 7, 2008, the FDA mandated new black box warnings for Aranesp relating to two clinical studies that concluded there was increased risk of death and faster tumor growth when administered to target a hemoglobin level of 12 g/dL in cancer patients not receiving chemotherapy or radiation therapy. This revised black box warning clarified that Aranesp should only be used in cancer patients with anemia specifically caused by chemotherapy, not for other causes of anemia. Amgen also issued a "Dear Healthcare Provider Letter" to medical providers advising of the revised Aranesp labeling. The Aranesp label, as approved by the FDA on or about November 19, 2008, is attached as Exhibit B.

101. As of February 6, 2010, the FDA approved a Risk Evaluation and Mitigation Strategy ("REMS") for Aranesp. The FDA required Amgen to develop a risk management program because studies have shown that Aranesp can increase the risk of tumor growth and shorten survival in patients with cancer, and increase the risk of heart attack, heart failure, stroke, and blood clots in other patients, including patients with chronic kidney failure. Aranesp's REMS requires Amgen to provide a Medication Guide explaining the risks and benefits of Aranesp to all patients receiving Aranesp. Amgen is also required to develop and publicize a program for healthcare professionals who prescribe ESAs like Aranesp to patients with cancer,

called ESA APPRISE. Amgen must ensure that only providers who have completed this program can prescribe or dispense ESAs to patients with cancer.

B. Procrit and Epogen (Epoetin Alfa)

102. Prior to becoming the Fortune 500 company that it currently is, Amgen was a fledgling biotech company struggling to finance the development of its drugs. One such drug under development was "epoetin alfa" ("EPO") – an ESA drug that would treat anemia in certain patients by stimulating the production of red blood cells.

103. In 1985, Amgen contracted with a subsidiary of Johnson & Johnson, Ortho Pharmaceutical Corporation ("J&J" or "Ortho") for financial and technical assistance in completing the development of, and FDA approval for, EPO. Among other things, Amgen and J&J agreed that Amgen would have exclusive rights to market EPO in the United States for use with dialysis patients; and J&J would have exclusive rights to market EPO for all other uses in the United States, including non-dialysis kidney patients. J&J also would have exclusive rights to market EPO outside of the United States (excepting China and Japan) for all uses. Amgen would market EPO under the name "Epogen," and J&J would market EPO under the name "Procrit." (J&J markets EPO under the name Procrit in the United States; but J&J markets EPO under different names internationally.)

104. When Amgen made its deal with J&J, EPO was primarily used to treat anemia in dialysis patients, which under the agreement would be Amgen's market. Thereafter, EPO was approved for many other uses, however, including the treatment of anemia suffered by cancer patients.

105. This oncology market for EPO was (and is) substantial indeed, but under the agreement this market belonged to J&J, selling EPO as the cancer drug Procrit. Moreover, when

EPO was used outside of dialysis (*e.g.*, in a patient with chronic kidney disease who was not yet on dialysis), Amgen owed J&J a royalty of between 5-10%.

106. Given this lucrative (but contractually barred) oncology anemia market, Amgen developed Aranesp, which was approved in 2001, as a new anemia drug that Amgen could market for use with oncology patients and non-dialysis kidney patients, without violating its agreement with J&J.

107. Since then, Amgen has aggressively and successfully marketed Aranesp as an alternative to Procrit, in an effort to increase sales and market share of Aranesp and to recapture the lost Procrit market.

108. Amgen also has marketed Aranesp as an alternative to its own drug Epogen, which as of 2003 was Amgen's best-selling drug with gross sales totaling $2.4 billion.

109. Amgen's cannibalization of its own Epogen sales laid the groundwork for Amgen to replace Epogen with Aranesp in anticipation of patent expiration issues and reimbursement changes that could make Aranesp more profitable for Amgen than Epogen.

110. Amgen, through its subsidiary Amgen Manufacturing, Limited (also previously known as Amgen Puerto Rico or "APR") manufactures Epogen and Procrit, as well as Aranesp. Amgen is responsible for the labeling of Aranesp and the other drugs it manufactures.

111. The FDA's black box warnings and 2010 guidance regarding Aranesp, referred to *supra*, also applied to Epogen and Procrit.

AMGEN'S NATIONAL FRAUD SCHEME TO OFFER OVERFILL IN ARANESP AS AN INDUCEMENT

A. The Use and Dosing of Aranesp

112. Aranesp is distributed by Amgen in single dose vials and single dose pre-filled syringes ("PFS") containing liquid solution with a predetermined concentration of the drug.

113. Vials may be used for administration of Aranesp by medical professionals while PFS packaging could be used by some medical professionals in their offices or by patients to administer their own medication on an outpatient basis.

114. Not all patients require the same level (strength) of Aranesp solution. For example, oncology patients typically require a higher dose of Aranesp than do nephrology patients. In order to accommodate the different clinical uses for Aranesp, Amgen distributes the drug in vials or syringes that contain different amounts of the drug – *e.g.*, 25 mcg (micrograms), 40 mcg, 60 mcg, 100 mcg, 150 mcg, 200 mcg, 300 mcg, or 500 mcg.

115. For each patient, the volume of liquid solution of Aranesp to be administered to the patient is roughly the same – usually 1.0 ml (milliliter) for the vials or 0.3-0.6 ml for the PFS packaging – but the amount of Aranesp administered to the patient (*i.e.*, the total micrograms of medicine) varies depending on the drug concentration within that liquid.

B. Aranesp Overfill

116. Although single-dose vials of Aranesp contemplate that a 1.0 ml injection will be administered to the patient, the actual volume of liquid solution in the vial *exceeds* 1.0 ml. This excess is known as "overfill."

117. According to the United States Pharmacopeia (the "USP"), injectable drug vials may include a "slight excess" beyond the label volume in order to permit withdrawal and administration of the labeled volume.

118. For the entire time that Aranesp has been on the market the USP has recommended overfill *up to* 10%. Thus, for a labeled fill volume of 1 ml, the USP contemplates overfill of no more than 0.1 for a total volume of 1.1 ml.

119. Although the USP statement is styled as a recommendation, overfill should be limited to the minimum amount necessary to obtain the prescribed dose of a drug to avoid, for example, overdosing patients. Overfill should not be administered to a patient, and doing so would result in misdosing.

120. As Amgen Northeast Regional Sales Director Mark Papineau explained in deposition testimony, "Overfill is the contents in the vial … that go above and beyond what is on the label that is the normal process for biologics in order for the average person to be able to get out whatever is on the label."

121. The overfill amounts contained in Amgen's ESA products, Aranesp and Epoetin Alfa (Epogen and Procrit), and the changes to the Epoetin Alfa overfill amounts, were issues of importance at the highest level within Amgen. By example, an e-mail dated January 6, 2006 from Edwin Mar, Senior Manager of Medical Information, to Helen Torley, Vice President and General Manager of Nephrology, and Leslie Mirani, Vice President of Sales, states: "In regards to your request to provide EPOGEN overfill historical information to [CEO] Kevin Sharer, these are the information I have available so far regarding EPOGEN 1.0 mL vial fill volumes."

122. The e-mail goes on to provide the overfill amounts for Epogen from 1993 through January 2006 as follows: (1993-Q4/2002) – 1.168 mL; (Q4/2002-Q1/2004) – 1.144 mL; and (Q1/2004 – present) – 1.111 mL.

123. Thus, when Aranesp was first introduced into the market, Epogen vials manufactured by Amgen contained 16.8% overfill, which was then reduced in 2002 to 14.4% overfill, then by 2004 to 11.1% overfill.

124. In 1999, Amgen set the initial overfill amount for Aranesp packaging at 16.8%, then soon increased the amount of Aranesp overfill to 17.7%.

125. The level of Aranesp overfill was a matter of concern to Amgen compliance and manufacturing employees. As Amgen's current Director of Regulatory Affairs, Cheryl Anderson, explained in an August 2000 e-mail to colleagues: "Considering that the EPO 1mL vial overfill = 0.168 +/- 0.04 and the USP recommendation is an overfill of 0.10 and the fact that one of our EPO distributors is being sued for double billing Medicare because of the ability to pool the EPO overfill and FDA required us to issue a Dear Doctor letter just 2/3 months ago warning users not to pool the EPO overfill, why are we proposing to increase the [ARA]NESP overfill even more than EPO?"

126. In fact, manufacturing and compliance personnel within Amgen recommended an almost immediate reduction of Aranesp overfill, shortly after Amgen began marketing Aranesp.

127. Similarly, in 2001, manufacturing personnel at Amgen recommended that the overfill in all products manufactured at Amgen Puerto Rico, including Epogen vials, be reduced from 16.8% to 10%.

128. Despite the concerns expressed about having too much overfill in Aranesp, for the launch of single use vials, the amount of overfill in Aranesp vials was *increased* above 16.8% and 17.7%.

129. According to an Amgen PowerPoint presentation, entitled "Update to Executive Committee," overfill in Aranesp vials was increased to 19% to assure success for launch of the Aranesp product in 2001. (The PowerPoint presentation also recommended decreasing the Aranesp overfill back to 16.8% in 2002, citing regulatory and manufacturing reasons, as well as a Department of Justice investigation into the overfilling of Epogen vials. The same document noted that reductions in overfill volume could have customer and reimbursement implications.).

130. As a result, at the launch of the Aranesp vial marketing campaign in 2001, Aranesp vials contained 90% more overfill than the 10% maximum overfill recommended by the USP.

131. Amgen did not advise the FDA of the increase in overfill in Aranesp vials to 19%, despite the fact that the increase was inconsistent with the Biologic License Application Amgen had obtained for Aranesp.

132. By comparison to the 19% overfill in Aranesp, PFS packaging of Aranesp contained considerably less overfill that was less than the USP 10% guideline.

133. By further comparison, although Amgen pegged the Aranesp overfill to Epogen overfill when it first manufactured Aranesp, by 2002, Amgen reduced Epogen overfill from 16.8% to 14.4%. By 2004, Amgen had reduced Epogen overfill to 11.1%.

134. Amgen made no corresponding reductions in Aranesp overfill despite the recommendation of the Amgen Global Operations Team that, as of April 11, 2002, fill volumes for Aranesp could "be reduced from 1.168 ml to the USP-recommended 1.10 ml" based on a three-year plan that would have ended with Aranesp overfill reduced to 10% in 2004.

135. Some time after the launch, Amgen resumed manufacturing Aranesp vials with 16.8% (or in some cases 17.7%) overfill, but Amgen never implemented the anticipated further reductions in Aranesp overfill, despite continuing concern within Amgen that Aranesp vials contained unnecessarily excessive overfill.

136. As of April 2005, the project to reduce Aranesp overfill was on hold pending an assessment to determine whether Aranesp overfill should be reduced "from a marketing standpoint."

137. Again, for example, in 2008, an internal company recommendation was made to decrease the overfill amounts contained in Aranesp vials. An Amgen PowerPoint presentation dated April 3, 2008, entitled "Overfill Reduction: Aranesp 1.0mL vials" recommends that the overfill amounts contained in Aranesp vials be decreased in two phases in order to reduce overfill amounts from 16.8% to 13%.

138. In the end the "marketing standpoint" won out over concerns of patient safety and compliance and manufacturing protocols. Amgen did not reduce the level of Aranesp overfill. Instead, Amgen maintained the level of Aranesp overfill so that Defendants could market the overfill, because the overfill was a necessary component of Aranesp's profitability versus the competing product Procrit (which Amgen also manufactured and for which Amgen held overfill to a lower amount).

C. The Economics of Overfill

139. Amgen's failure to reduce Aranesp overfill was part of Defendants' scheme to increase sales of Aranesp, Amgen's share of the EPO market, and INN's profits, by offering the Aranesp overfill as an economic incentive to medical providers, in violation of the law, including the Anti-Kickback Statute and the Federal FCA.

140. Aranesp overfill has value because Aranesp purchasers are charged for the drug based upon the *labeled* concentration and dosage. Overfill is not reflected on the label and purchasers are *not* charged for the overfill that they receive – *i.e.*, they do not pay for the extra micrograms of drug that are present in the overfill.

141. For example, if a physician buys a 1.0 ml single-dose vial containing a 60-mcg concentration of Aranesp, then the physician only pays Amgen (or ASD Healthcare or another drug provider) for 60 mcg worth of the drug. The physician does not pay for the additional 10.08

mcg of Aranesp present in the 0.168 ml of overfill for that particular 60-mcg vial. Likewise, a physician purchasing a 300-mcg vial of Aranesp would not pay for the extra 50.4 mcg of drug in the overfill for that vial.

142. Not charging for the overfill is consistent with the intended purpose of overfill, which is to ensure that the labeled dose of the medication can be administered. Overfill itself is not intended to be administered.

143. The amount of drug product in a vial of injectable drugs manufactured by Amgen (such as Aranesp) should include the labeled volume, plus the amount required because of drug product that may not be drawn out due to the functioning of the needle or the vial (which is sometimes referred to as "hold up volume" or "HUV").

144. When single use injectable drug vials are filled properly in such a manner, there typically should be little or no overfill that can be extracted from the vial, because the fill volume of the vial will consist of the labeled dosage and some additional liquid that is expected to stick (or be "held up") in the needle or the vial.

145. However, under Defendants' unlawful marketing scheme, Aranesp vials as manufactured by Amgen contained more overfill than was required to provide the labeled dose and HUV, so that Defendants were able to use the overfill to induce medical providers to submit claims to Government Health Care Programs for the free Aranesp overfill.

146. Defendants' efforts to induce the filing of claims relating to Aranesp overfill were successful. Medical providers submitted claims to Medicare and other Government Healthcare Programs to obtain money for the Aranesp overfill (despite the fact that the overfill had not cost the providers anything), often based on standing orders or protocols to submit overfill claims with respect to every patient, with no basis in medical necessity.

147. Amgen in fact knew that it was improper for medical providers to file such claims. Among other things, Amgen's own reimbursement consultant, a company called Covance, made clear to Amgen personnel in 2004 that medical providers could not bill for overfill:

> Fundamentally, overfill is not purchased product and should not be billed. If one argued that it was purchased, then the logic would be that payers' payment per unit would need to be readjusted to account for all the product in a vial, not what the vial's labeled amount is. . . . As for the purchaser's POV [point-of-view], I can see their wanting to bill for all product the[y] 'received,' but in fact they are only to bill for what they 'purchased.' Billing for non-purchased amount is the same as billing for samples. They did not incur the cost of these extra units, and therefore cannot bill for them. Your price is for the amount of the vial as labeled. According to Medicare regs, when they buy a 100 mcg vial of Aranesp, they purchased 100 mcgs, and they can only bill for the mcgs they purchased according to the package label, not what the vial might have contained beyond that.

148. Moreover, beginning in 2005, certain Government Health Care Programs including Medicare based the amount they would reimburse for drugs (such as Aranesp) on average sales price ("ASP") data to be reported by drug manufacturers (such as Amgen). Although Amgen knew that the Aranesp overfill materially affected medical providers' cost for Aranesp (such that the providers were, in essence paying less for Aranesp) Amgen did not include or account for the overfill in the Aranesp ASP pricing information it certified to Medicare.

149. In many cases, as well, Defendants' promotion of the filing of Medicare and other claims relating to Aranesp overfill involved efforts to induce medical providers to seek reimbursement for the maximum overfill expected to be in each Aranesp vial when, in fact, it would not have been possible for that much overfill to be withdrawn from every vial, based on

Amgen's own "tests" and other "justifications" for why an overfill level above the USP recommendation was appropriate for Aranesp single use vials.

150. Amgen knew, as well, from data received from customers and other sources that medical providers could not extract and administer all of the Aranesp overfill from each vial, yet Defendants encouraged medical providers to submit claims based on across-the-board billing for all (or virtually all) the Aranesp overfill, even though it was not possible that the medical providers actually administered those "doses" to patients, which would have been medically unnecessary in any event.

151. Thus, Defendants not only induced medical providers to submit claims for Aranesp overfill despite knowledge that Government Health Care Programs should not be charged as if the medical providers had paid for the overfill, they also induced and assisted medical providers in filing claims that were not based in medical necessity, as well as claims for Aranesp that was not actually administered.

152. Moreover, by failing to consider the Aranesp overfill that Defendants marketed to medical providers as part of its ASP computations, Amgen fraudulently certified to Medicare an ASP that was too high and by so doing, assured that the reimbursement amount paid by Government Health Care Programs such as Medicare would be fraudulently overstated for every submitted Aranesp claim.

153. A motive for Amgen to commit this misconduct was the "economics" of Aranesp versus Procrit, which demonstrate that Aranesp could be more costly to purchasers unless it was assumed that the purchasers would bill Medicare for all of the Aranesp overfill.

154. For example, the customer "economics" spreadsheet created by an Amgen employee attached as Exhibit H demonstrates that Procrit is more profitable for the medical

provider than Aranesp unless and until overfill is considered and it is assumed that Medicare claims will be submitted for all of the stated overfill.

155. The spreadsheet also demonstrates that Amgen's own projections indicated that Aranesp could be more expensive to Medicare than Procrit was unless reimbursements for overfill amounts were included.

D. Unlawful Promotion of and Billing for Aranesp "Overfill"

156. Medicare provides reimbursement for Aranesp based on the number of micrograms of Aranesp that were actually administered to the patient. The reimbursement amount was based on 5-microgram units when Aranesp single unit vials were first sold (from 2001 to the beginning of 2004) and based on 1-microgram units thereafter.

157. In unusual circumstances, such as when a dose consisting of part of an Aranesp vial might be delivered, Medicare regulations regarding unusable product that is considered necessary "waste" can permit a medical provider to submit a claim for reimbursement of up to the *labeled* amount on the vial, but that claim would not be allowed to include a request for reimbursement relating to the overfill.

158. Defendants have conspired with each other, and with providers and others to defraud both governmental (federal and state) and private health insurance programs by encouraging Aranesp purchasers to seek reimbursement for the additional micrograms of Aranesp contained in the overfill. This overbilling is improper for a number of reasons, including:

(a) the Aranesp purchasers did not actually pay for the overfill micrograms of drug;

(b) the Aranesp purchasers often do not administer the "overfill micrograms" of drug to their patients because to do so would be unreasonable and medically unnecessary, but they nevertheless bill for it;

(c) when the overfill has been administered, it is often unreasonable and medically unnecessary and posed a danger to patient health and safety, as is confirmed by the black box warnings and other studies referenced in this Complaint;

(d) the Aranesp purchasers have submitted claims for Aranesp overfill in excess of what they realistically could have drawn from the vials and administered; and

(e) some providers would pool the overfill from several vials of Aranesp until there was sufficient volume from the overfill to constitute a separate dose. The providers would then bill for the additional dose without disclosing that they had, in essence, obtained the dose for free.

159. Around the launch of Aranesp, in May 2001, Amgen commissioned an "Epogen Vial Study," that concluded that anemia managers and renal administrators at freestanding dialysis clinics were accustomed to recovering costs for some of the overfill from multi-use vials of Epogen (approximately 5% to 18%) in order to increase their centers' profits.

160. Consistent with the results of Amgen's study of what purchasers used to Epogen multiuse vials might want, Defendants sold Aranesp single use vials based on economic analyses for Aranesp purchases including "overfill discounts" or "overfill credits" that were used throughout the United States by the Amgen sales force to calculate potential profits for medical providers from putting their patients on Aranesp.

161. For example, an Amgen document entitled "WAP to AWP Pricing," which was authored by a sales representative based in Tennessee, contains an Aranesp and Procrit cost and revenue comparison and reflects a line item for "Overfill at 10%" credit for Aranesp purchases of 100 mcg vials. The analysis calculates a medical provider's potential profit in purchasing Aranesp based on Medicare reimbursement rates, and includes a dollar credit for "Overfill at 10%." This credit values 10% of overfill in a 100 mcg vial at $47.39. This economic worksheet was electronically mailed on September 16, 2003 to Amgen sales representatives located in Louisiana, Maine, Massachusetts, New Hampshire, New York, Rhode Island, Tennessee, Vermont and the District of Columbia.

162. Amgen sales representatives, corporate account managers, district sales managers, and regional sales directors individualized these economic revenue models for specific physician practices or hospital accounts where that Amgen employee was marketing Aranesp. Further examples of economic analyses that included the overfill inducements that were distributed or used nationally include the following:

(a) An economic cost and revenue analysis completed for Balboa Nephrology Medical Group, a nephrology group with 13 clinical offices in San Diego, California, reflects a 16.8% overfill – all units credit versus a 11.1% overfill credit for Procrit;

(b) An e-mail dated February 7, 2005 to Amgen Northeast Regional Sales Director Mark Papineau from a New York City-based sales representative attaching a "clinic spreadsheet tool" comparing Aranesp to Procrit costs and reimbursements. The spreadsheet compares reimbursements for the Aranesp vials at 10% overfill and at 15% overfill against Procrit, as explained in Joe

Campagnuolo's cover e-mail. Within three days, Northeast Regional Sales Director Mark Papineau electronically forwarded this clinic reimbursement spreadsheet tool to the entire Northeast Management Team with the admonition: "This is truly an FYI. DO NOT SHARE WITH CUSTOMERS;"

(c) A "Neu Ara Plus" Aranesp contract analysis for St. Luke's Hospital in New York, New York, that reflects an overfill credit for Aranesp purchases; and

(d) An e-mail dated August 2, 2005 from an Oklahoma-based sales representative to a District Sales Manager referencing conversations – at a couple of hospitals – that there is more overfill with the Aranesp vial, while there is no overfill with the "Singleject [Aranesp PFS syringe]… 3 mcgs for free for Aranesp and they can bill for it."

164. During the time that Relator was employed by Amgen, she learned that Amgen PSRs would advocate to customers the increased profits that could be made if the customers were to seek reimbursement for the "overfill micrograms" of Aranesp in the single-dose vials that they had purchased.

165. The Relator has spreadsheets from her employment with Amgen that are examples of how the overfill was calculated and advocated by representatives and management. One example is attached as Exhibit E (showing, among other things, that Amgen encouraged medical providers to submit claims that would have resulted in billing Medicare for 99.2% of the overfill contained in 60mcg, 150mcg, and 300mcg vials of Aranesp). This spreadsheet includes computations of "Practice Cost Revenue Model," including assessment of revenues that medical providers could realize from Aranesp overfill. *See, e.g., id.* at 2 (displaying boxes for Procrit and

Aranesp units, AWP, and AWP + Overfill); *id.* at 3 (presenting tabular computations of "Aranesp Vs. Procrit and Overfill").

166. As another example, a spreadsheet called "2006 Comprehensive Reimbursement Worksheet" was sent from Amgen employee Tiffany Gaetano to Amgen District Manager Louis Deppe on January 21, 2006. In the cover e-mail, Ms. Gaetano explained that she had updated the spreadsheet so that one worksheet would "automatically include overfill in the calculations" as different vial sizes of Aranesp and Procrit were entered because many Aranesp sales representatives have customers who "utilize overfill." The concept behind the spreadsheet was that any Aranesp sales representative could compute the "Net Total Cost Recovery" in dollars of various dosings of Aranesp versus Procrit, simply by changing the "monthly dose" shown for each drug. Further, to compute the "Total Annual Impact" on the customer's office, the Amgen sales representative could also input a personalized number for the "total patients being treated."

167. The spreadsheet itself includes two worksheets labeled "ASP training" and "ASP training (with overfill)." Both worksheets include the reimbursement amount for Aranesp based on ASP+6% per mcg, with the key difference being that the first worksheet shows the amount $2.989 per mcg, while the second worksheet takes that amount and *multiplies* it by 1.168 to come up with a reimbursement amount of $3.491 per mcg. *See* Exhibits C ("ASP training") and D ("ASP training (with overfill)").

168. To further illustrate this concept, the spreadsheets have been printed to show the formulas underlying each cell. In the first worksheet, the cell for "ASP+6% per mcg/unit" (C13) contains the value "2.989." In the second worksheet, the same cell (C13) contains the value "1.168*2.989." Similar adjustments are made in the next cell (D13) to reflect Procrit overfill of

11.1%. *See* Exhibits F ("ASP training" – cell view) and G ("ASP training (with overfill)" – cell view).

169. As the worksheets indicate, Aranesp was less profitable for customers *unless* the Aranesp overfill was taken into account. *See* Exhibits C and D. If the customer stayed with Procrit (without overfill), based on the amounts Ms. Gaetano put in her spreadsheet, the "annual impact" – *i.e.*, profit – on dosing 50 patients with 40 units monthly would be about $15,000 (compared to about $7,300 for Aranesp). With overfill, the profits rise dramatically, to almost $39,000 per year using Procrit and *more than $43,000 per year* for Aranesp – with almost all of the difference coming from increased Medicare reimbursements based on the overfill.

170. Although the spreadsheet says "For internal Amgen Educational Purposes Only, Not for use with customers," such admonitions to keep projections relating to the "economics" of Aranesp versus Procrit, including overfill, internal were not followed by Defendants.

171. And, although Amgen's own position is that it would not be possible to withdraw all 16.8% of the overfill in any Aranesp vial (including that, according to Amgen, the reason so much overfill is required in Aranesp vials is because the overfill is not accessible), the economic projection information used with Aranesp customers modeled the profit that customers would achieve from submission of Medicare claims for all of the overfill, thereby encouraging and instructing customers to submit such fraudulent claims.

172. This spreadsheet also illustrates that Amgen did not consider overfill in providing certified ASP computations to The Centers for Medicare & Medicaid Services ("CMS") regarding Aranesp. It was created in January 2006. The "ASP training" worksheet reflects a Medicare reimbursement rate of ASP + 6% that is equal to $2.989 per Aranesp mcg (which is

increased by an additional 16.8% on the "ASP training (with overfill)" spreadsheet to reflect the value of the Aranesp overfill that Amgen gives to medical providers).

173. Spreadsheets such as the ones included as exhibits to this Complaint were created in order to sell Aranesp – and they were used by Amgen and INN representatives in selling Aranesp to customers in meetings set up to discuss "economics" or to "talk about the numbers," or to "convert" accounts.

174. Sometimes, an INN representative presented the "economics" of Aranesp (including overfill) to customers to make it appear as if Amgen was not participating in such discussions. Other times, Amgen representatives conducted or participated in the discussions. In either case, all Defendants knew what was occurring.

175. In addition, the presentation of the "economics" spreadsheets to customers was to take place using a laptop or was to be written on a napkin or paper that was not left behind, so that the customer could view the information, but the information would not remain in the customer's records. On occasion, however, customer requests for the model to be provided were honored by Defendants.

176. Relator also is aware of other PSRs and INN and IPN employees discussing with customers/providers how to fill out the Form CMS 1500 claim form (attached as Exhibit K) – they told the customer to simply write down for the dose they purportedly "administered" an amount that would include the overfill, on the Form CMS 1500 claim form, even if they did not actually administer the overfill amount. These instructions were intended so that the medical provider "could pass an audit" by Medicare.

177. Indeed, the standard materials available to Amgen sales representatives included "mock-ups" of Form 1500 Medicare claim forms so that they could assist with even the claims filing and "walk the claim through" the reimbursement process for the customer.

178. Although Relator never engaged in the practice of promoting "overfill" billing, she had numerous communications with other PSRs from around the country confirming that the practice existed and that other Amgen sales representatives engaged in the practice, and she personally observed it when she called on the multispecialty clinic, Bend Memorial Clinic, as well as major hospital systems in her territory with the oncology sales representatives.

179. For example, Chris Coates of Amgen reported to Relator that Balboa Nephrology of San Diego, California, had resolved to capture overfill. Between March and August 2004, Balboa Nephrology, 65% of whose patients used Medicare as their primary insurance, spent almost $700,000 on Aranesp.

180. Moreover, Relator is aware that other Aranesp customers did, in fact, engage in "overfill billing."

181. Furthermore, upper management of Amgen – including the National Sales Director ("NSD") and the Director of Marketing – were aware of the practice of advocating "overfill billing" to customers and did nothing to prevent it. Indeed, the Regional Sales Director (who reports to the NSD) authored spreadsheets that included overfill computations. Relator also witnessed conversations in meetings regarding overfill involving the NSD and Director of Marketing (among other management).

182. Amgen PSRs would often complain about overfill because they said J&J was actively marketing Procrit with promotional materials that advertised the use of overfill and the Amgen representatives wanted some similar materials to market Aranesp overfill.

183. The response of Amgen management was to say that Amgen could not come out with official company materials on overfill marketing but, instead, the PSRs could talk about how medical providers could bill for Aranesp overfill in private with customers and could let INN representatives discuss the "economics" of Aranesp, including billing for overfill, with customers.

184. Nevertheless, in order to have some materials to present to customers, some Aranesp sales representatives, district managers, and regional sales directors prepared detailed spreadsheets (ostensibly labeled "For Information Only") that expressly calculated the additional (and significant) revenue/profit that could be made by customers if they sought reimbursement for the "overfill micrograms" of Aranesp. They showed these spreadsheets to their customers during their office visits to market Aranesp – and, in particular, to market the greater profits that could be made on Aranesp as compared to the competing drug Procrit if reimbursement were sought for Aranesp "overfill."

185. Amgen's own *internal* spreadsheets also show that overfill had direct cash value in terms of the amount of reimbursement that a physician could receive. They compare "Aranesp" Medicare Allowable with a higher "Aranesp with Overfill" Medicare Allowable.

186. An INN nephrology "backgrounder" advises—under the heading "Over Flow Usage in Aranesp Vials"—that "You could also give the full 116 mcg (instead of 100mcg) bill and be reimbursed for the entire 116mcg."

187. One clinician who spoke with Amy Oliver, an Amgen Oncology Account Manager, asked if Aranesp contained Overfill "because 'that's how we make money.'"

188. Angela Miele, an INN account representative who used to work for Amgen wrote that a physician told her that the physician's rebate was higher for another drug because she was

"adding in the overfill," and then wrote "I take that out of my original analysis [when marketing Aranesp] to level the playing field [in comparison to other drugs]. Then you can speak to the fact that Ara has 16% overfill afterwards." Miele also wrote to a physician that "Providing Aranesp to your CKD patients could help pay for the private school."

189. To demonstrate the potential profitability of Aranesp "overfill" billing, the "overfill spreadsheets" typically would compare the reimbursement amounts and spreads for Aranesp + overfill to the reimbursement amounts and spreads for Procrit + overfill.

190. Amgen management not only saw but, in some cases, authored these spreadsheets, and did nothing to prevent the Amgen sales force from using them with their Aranesp accounts.

191. In fact, although the company's official "line" was that overfill – and comparative economics – were not to be discussed by Amgen personnel, Amgen sales representatives knew that they could ask to receive the "overfill spreadsheets" or similar information if they thought it could help sell Aranesp to an account. For example, on July 7, 2004, Amgen San Francisco District Sales Manager Jeremy Jaggi wrote an e-mail to Mark Bachleda (Amgen Senior Marketing Manager), copying Ray Chow, Claes Hornstrand, and Alex Lyons, entitled "Procrit Overfill Economics," which said:

> Numerous reports are coming in recently regarding the promotion of Procrit overfill and a 5% benefit over Aranesp. . . . Do you have a spreadsheet analyzing head to head dosing with the overfill for my background?

192. Amgen (and the other Defendants, as discussed below) knew they could influence the purchaser's choice of drug by using the "overfill" profit contained in each vial of Aranesp

compared to that for Procrit or Epogen. Amgen also knew it could manipulate the "overfill" economics because Amgen manufactured all three drugs.

193. This practice of advocating "overfill billing" to Amgen's customers constituted a form of free drug sample or "liquid kickback" in every vial. Yet, unlike traditional free drug samples which are heavily regulated – *i.e.*, they must be carefully accounted for by drug companies and cannot be the basis for governmental reimbursement – the free amounts of overfill found in every Aranesp vial were provided by Amgen without any such reporting requirements. When Amgen advocated, and conspired with other Defendants and their customers, to engage in "overfill billing," however, the unlawful effect was no different than it would have been had Amgen provided its customers with free Aranesp samples and then encouraged them to seek reimbursement for them from Government Health Care Programs.

194. Amgen's intention to exploit "overfill billing" as a means of gaining new customers and market share is further evidenced by the unusually large quantity of overfill found in the Aranesp vials, especially as compared to that in the multi-dose vials of Procrit and Epogen.

195. If anything, one would reasonably expect there to be more overfill in a multi-use vial than in a single use vial because with multiple injections there presumably is some risk of greater spillage, wastage, etc.

196. As is discussed in more detail below, Defendants INN and ASD Healthcare also improperly advocated and encouraged its/Amgen's customers to seek reimbursement for Aranesp overfill, in the course of seeking to achieve the goal described at a March 16, 2004 "Amgen-INN Strategy Meeting" as being to "Convert Procrit® users to Aranesp®."

197. Similarly, for example, on March 26 and 27, 2004, Relator attended a weekend seminar in Carmel, California, that was "sponsored" by INN, at which INN and IPN

representatives openly pushed physicians and office managers to bill for overfill when seeking reimbursement. The INN representatives advised the seminar attendees that as long as the overfill quantities were included on the patients' charts as having been administered – even though they were *not* administered – then the overfill reimbursement supposedly would pass an audit.

198. Defendant Amgen was aware that promoting billing of "overfill" in Aranesp vials was unlawful, but did it anyway. Numerous communications, meetings, e-mails and other documents reflect Amgen's overfill scheme and Amgen's knowledge of both the scheme and its fraudulent nature.

199. For example, Amgen's internal "compliance" mantra was that employees could not "proactively" discuss "overfill" with customers, but instead were to provide the customers with a "Business Reply Card" or "BRC" that would enable the customers to obtain a letter from Amgen's Medical Information department stating the amount of overfill in Aranesp vials.

200. Although Amgen's Medical Affairs or Information Department, and not the sales force, purportedly distributed these overfill letters to medical providers, the sales force had access to the overfill letters as one of their sales "tools." An Amgen document, entitled "Aranesp/Epogen/Sensipar Tools, Benefits and Strategies," lists the Aranesp overfill guidelines as among the *economic* tools that were accessible to the sales force in Microsoft Word format.

201. Moreover, the Amgen sales staff knew exactly why customers were requesting information about overfill. As New England Regional Sales Manager Mark Papineau testified:

> Q. Do you have any understanding as to why customers would be requesting the amount of overfill in Amgen's products?
> A. For certain customers, yes.
> Q. And what is that?

A. They would tell us that they were billing for it, they were using it, administering it and billing for it.

202. Nevertheless, despite the fact that overfill was, computed and discussed, Mr. Papineau explained that the official policy of Amgen remained that no one ever "proactively" discussed overfill:

Q. Why would a sales representative not be permitted to discuss overfill?
A. It's one of our policies.
Q. Is it written down somewhere?
A. Yes.
Q. Where would I find it?
A. Terri Zwicker.
Q. Is it a specific stand-alone policy or is it part of some larger policy?
A. I'm not sure of the details on that, but I know it has been reiterated many times that we are not to discuss overfill, proactively discuss overfill with customers.
Q. When you say proactively, are representatives permitted to discuss it reactively?
A. They're permitted to say, doctor, I'm not permitted to discuss overfill, that's a compliance violation, and I have to refer you to medical affairs if you want more information and I need for you to sign this card and they'll have it sent to you. So that's to the extent that they would be able to talk about it.

203. In response to further questioning, Mr. Papineau added, "It was clear to the [Amgen] representatives that they should not be selling or promoting on overfill and/or the profit of our medications. Whether those communications came out together or separate, I just don't know, but it was clearly put out there to the team." Mr. Papineau could not recall when the directives came out, but he asserted that every year he would give a presentation to his team and he would include a presentation about "making sure we're 100 percent compliant, and that includes no discussions on overfill, no discussions on profit." According to Mr. Papineau, it would be better to lose a customer than to discuss overfill.

204. Nevertheless, Mr. Papineau stated that Amgen sales representatives are permitted to talk to customers about overfill in the context of the BRC card, but only to say "that they can't talk about overfill." However, Amgen recently has changed its policies to permit more leeway on overfill. In the past, Amgen sales representatives purportedly were not even supposed to complete the BRC and were required to provide the BRC to the customer, so the customer could complete the request for overfill information. Amgen now permits its sales representatives to complete the BRC request for overfill.

205. Other evidence, in fact, supports that Amgen sales representatives had the "Medical Information Overfill Letter" at their disposal as a sales/economics tool, at the same time that Amgen sales representatives were discussing overfill and economics in detail with various customers.

E. Examples of Defendants' Misconduct in Relation to Particular Medical Providers

206. By way of example, Relator provides the following details regarding various nephrology groups throughout the United States that Defendants encouraged to submit false claims based on Aranesp dosing that was not medically necessary, that was not based on the doctors' legitimate medical judgment, or that was not actually provided to patients.

207. Defendants' conduct similarly affected other medical providers throughout the country. Claims data received to date support that providers throughout the country who were subject to Defendants' targeted sales efforts had a pattern of submitting claims to Government Healthcare Programs, including claims paid by Medicare or other federal funds, for close to 100% overfill from Aranesp vials.

1. Balboa Nephrology

208. Most of the patients of Balboa Nephrology Medical Group ("Balboa") in San Diego, California – 65% – use Medicare as their primary insurance. Amgen induced Balboa to bill Medicare for Aranesp overfill.

209. Amgen successfully converted Balboa from purchasing mostly Procrit to purchasing mostly Aranesp, between around 2002 and late 2004.

210. Following Balboa's conversion to Aranesp, and at the direction of Amgen representatives, Balboa submitted claims to Medicare relating to Aranesp overfill purportedly administered to some of its patients.

211. Amgen caused medical providers affiliated with Balboa to submit false certifications to Medicare that they were in compliance with state and federal laws, including the federal Anti-Kickback Statute. Defendants also provided particular incentives to Balboa physicians, including Steve Steinberg, who served on Amgen's Steering Committee and was a trained Amgen speaker. INN and Amgen jointly conducted a Practice Advisory Board at Balboa with Dr. Steinberg on October 30, 2003. INN offered Balboa physicians honoraria to participate in a meeting on November 6, 2004 at Huntington Beach.

212. Around late 2004 and early 2005, after aggressive marketing by Ortho Biotech, Balboa considered switching some of its patients from Aranesp back to Procrit. Amgen and INN employees actively discussed the economics of this decision and lobbied against it. For example, Claes Hornstrand created a model comparing the economics of using Procrit rather than Aranesp at Balboa, and he discussed the model by e-mail with his Amgen colleagues, Ray Chow and Daniel Brox. Mr. Hornstrand included overfill in the model's profitability calculations.

213. Amgen employees, including Julie Preston, Lisa Sherman, and Messrs. Hornstrand and Brox, also brainstormed openly with Gary Inglese of INN about the economics of Balboa's use of Aranesp.

214. During this time, Mr. Hornstrand also wrote to his fellow Amgen employees that the "critical question" with determining the economics for Balboa was "whether they do double-dipping or full pull." These are two methods by which overfill can be extracted from a vial and/or administered to patients. Double-dipping – also known as pooling – involves administering part of the contents of the vial to one patient, then re-entering the vial in order to extract and administer the rest of the vial to one or more other patients. Full pull involves withdrawing the entire amount of the vial, including as much of the overfill as can be withdrawn, and billing for the face-labeled amount plus overfill.

215. Ms. Preston, an Amgen sales representative who was involved in converting Balboa from Procrit to Aranesp, circulated a spreadsheet containing an economic analysis of Aranesp pricing under Balboa's Platinum Plus PACT Agreement for purchasing Aranesp.

216. The spreadsheet, attached hereto as Exhibit H, compares the pricing and reimbursement of Aranesp to the pricing and reimbursement of Procrit, including reimbursement for overfill for both drugs. The spreadsheet compares 16.8% overfill for Aranesp against 11.1% overfill for Procrit. The analysis also reflects a 20% off-invoice discount and an additional 4.5% discount from INN. Ms. Preston e-mailed the spreadsheet to Amgen employees, and also to Gary Inglese of INN, on February 11, 2005.

217. Amgen marketing and sales representatives advised the Clinics Manager and other Balboa staff that Aranesp was more profitable for Balboa than Procrit, by comparing the overfill amounts contained in Aranesp and Procrit vials. Amgen employees gave presentations to Balboa staff on a laptop about using Aranesp rather than Procrit, and in those presentations they compared Aranesp overfill to Procrit overfill, sometimes using spreadsheets. The Amgen sales representatives did not leave these overfill comparisons with the Balboa staff; they only permitted the Balboa staff to view the comparisons on the laptop computers.

218. Balboa employees were advised by Amgen representatives that billing for the overfill contained in Aranesp vials was not illegal.

219. Balboa communicated to Chris Coates of Amgen that it intended to capture Aranesp overfill, and Mr. Coates relayed that information to Relator.

220. Balboa issued a standing order for doctors to write patient orders for Aranesp in an amount that was 10% more than the standard dosage that would otherwise have been administered, after which the Medical Assistants were to try to draw up as much of the Aranesp vial as possible (which, according to the protocol, would usually increase the dosage by 5% or 10%), such that Medicare would be billed for the amount withdrawn, including the overfill. The order, in effect, mandated an across-the-board protocol at Balboa to increase dosages and to administer and bill for Aranesp overfill, for every patient that received Aranesp.

221. The Balboa standing order falsely stated that Medicare approved of this practice. The order also was in effect even after the FDA's black box warnings that warned of serious injury or death that could occur if patients received excess doses of Aranesp.

2. Bronx Westchester Medical Group

222. From 2004 through 2009, Amgen offered inducement, in the form of free Aranesp overfill, to Bronx Westchester Medical Group, located in Bronx, New York. Amgen representatives offered the overfill to Bronx Westchester Medical Group in order to prevent it from buying and administering Procrit.

223. Amgen sales representatives told a physician affiliated with the Bronx Westchester Medical Group about the overfill amounts contained in Aranesp vials. The Amgen sales representatives also told the physician that the practice could bill for the free overfill as a means to profit from administering Aranesp.

224. The Aranesp overfill was a "selling point" for Bronx Westchester Medical Group and dissuaded the practice from buying Procrit. The physician was shown economic analyses comparing Aranesp and Procrit and potential overfill profits by Amgen sales representatives. Amgen sales representatives never allowed the physician to keep those economic analyses but would only permit him to view them while an Amgen sales representative was present.

225. During the time that Bronx Westchester Medical Group was considering converting to Procrit, Amgen sales representatives also facilitated telephone calls or meetings between other medical providers, INN representatives, and Bronx Westchester Medical Group employees to pitch Aranesp as a lower-cost alternative to Procrit.

226. Amgen employees instructed the physician about how Bronx Westchester Medical Center should retrieve the overfill from the Aranesp vials and how the practice should bill the insurers, including Medicare and Medicaid, for the overfill.

227. Amgen also used the sham relationship between itself and INN to conspire with INN to offer overfill inducements to a nephrologist affiliated with Bronx Westchester, who met with an INN Strategic Account Manager ("SAM") who promoted Aranesp. The doctor stated that the INN SAM promoted the free overfill in Aranesp vials as a means for his practice to make profits.

228. The nephrologist further stated that he believed INN to be affiliated with Amgen and that INN SAMs were Amgen employees because of how heavily they pushed him to buy Aranesp. A July 19, 2004 INN PowerPoint, entitled "INN Update," confirms that an INN SAM and Amgen PSR jointly called on this Bronx Westchester nephrologist to pitch Aranesp.

229. At the direction of Amgen's sales representatives and INN representatives, physicians associated with the Bronx Westchester Medical Group billed third-party payors,

including Medicare and the New York Medicaid Program, for the free product it received from Amgen in the amount of 15% overfill in each Aranesp labeled dose. For example, for each 100 mcg vial of Aranesp that the practice purchased from Defendants, Bronx Westchester Medical Group's physicians billed 115 mcg, or 15% over the labeled dosage to the New York Medicaid program.

230. From August 10, 2004 to May 29, 2009, physicians affiliated with Bronx Westchester Medical Group submitted claims for reimbursement for the overfill contained in Aranesp vials to the New York Medicaid and Medicare programs. For the aforementioned time period, physicians affiliated with Bronx Westchester Medical Group submitted at least 139 separate claims for the overfill contained in Aranesp vials, amounting to at least $21,000 in Medicaid reimbursements paid by the New York Medicaid program for claims that were ineligible for payment. Some or all of these claims were "crossover" claims that were also reimbursed by federal Medicare funds.

231. These included, for example, six claims by one physician affiliated with Bronx Westchester in January and February of 2005 totaling $1299.18 in Medicaid payments and $4881.52 in federal Medicare payments, all of which included overfill. Another example are 45 claims by another Bronx Westchester-affiliated physician, each of which was submitted based on 115 mcg of Aranesp (thus, including a standard full dose of overfill), from 2007 to 2009, totaling $3,167.77 in Medicaid payments and $12,569.21 in federal Medicare payments

3. California Kidney Medical Group

232. For the relevant time period of this Complaint, California Kidney Medical Group ("California Kidney") billed Government Healthcare Programs for the free overfill it received from Amgen, at the rate of 15% more than each Aranesp vial's labeled dosage. For example,

with respect to each 100 mcg vial of Aranesp it purchased from Amgen, California Kidney billed 115 mcgs, or 15% over the labeled dosage, to the California MediCal program. These claims for 115% of a 1 mL vial are factually false, as it is not possible to withdraw 15% overfill from a single dose vial.

233. Moreover, just as California Kidney could not, in fact, retrieve 15% additional from every vial of Aranesp, it would also not be medically necessary to dose every patient who would otherwise have received 100 mcgs of Aranesp with 15% more Aranesp.

234. Such dosing was the practice at California Kidney, with assistance from Defendants. The files of INN sales representative Shelly Huttar contain an Inter Office Memorandum issued to California Kidney physicians and front office medical assistants on January 25, 2005, explaining that California Kidney had "received information from Amgen's medical information department about the overfill amount in an Aranesp vial. The amount of overfill is 16.8%. Please note that overfill is only VIALS only and that syringes do not have overfill."

235. The Memorandum thereafter included a table showing labeled Aranesp "DOSE" (based on standard Aranesp vial sizes) and "OVERFILL 16.8%" (based on multiplying the standard Aranesp vial size by 16.8%) and "Superbill/Progress Note" (which shows a rounded amount that could be billed in 5 mcg increments) as follows:

DOSE	OVERFILL 16.8%	Superbill/Progress Note
25 mcg	4.2	25 mcg
40 mcg	6.72	45 mcg
60 mcg	10.08	70 mcg
100 mcg	16.8	115 mcg
150 mcg	25.20	175 mcg
200 mcg	33.6	230 mcg
300 mcg	50.4	350 mcg

236. "Superbill" refers to a billing amount and "progress note" refers to notes. Accordingly, this Memorandum instructs California Kidney physicians and front office medical assistants to bill for and record amounts for Aranesp doses *including* overfill, when the intended dose was actually the labeled volume of Aranesp. For example, when a patient was to receive an Aranesp dose of 60 mcg, the billing and progress notes for that patient would indicate that 70 mcg had been administered and should be reimbursed.

237. Consistent with the Memorandum, California Kidney submitted claims to Government Healthcare Programs, including Medicare and Medicaid programs funded by the federal government, that were inflated by a standard amount of "overfill" that California Kidney did not pay for and did not administer. In other words, California Kidney's Medicare claims were false because the Aranesp dosage reported to Medicare was medically unnecessary and/or not actually administered.

238. As a result of Defendants' actions, California Kidney submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

4. Dallas Nephrology Associates

239. The account of Dallas Nephrology Associates ("DNA") was targeted by senior Amgen management in 2004 and 2006 through what were known as sales "blitzes," because it

was one of the largest and most influential nephrology practices in the United States. Such blitzes would provide a forum for important customers like DNA to discuss economic and reimbursement issues with senior Amgen management.

240. DNA received its own "special" contract from Defendants that provided an extra two or three percent discount just for DNA. Although there was internal discussion at Amgen that offering a better deal only to DNA through INN was not legal, Leslie Mirani approved the special pricing for DNA.

241. As a result of Defendants' actions, DNA submitted false and fraudulent claims for reimbursement to Medicare and Medicaid

5. Mid-Atlantic Nephrology Associates

242. Mid-Atlantic Nephrology Associates ("MANA") converted to 100% Aranesp use based on Defendants' aggressive sales tactics.

243. As MANA nurse Sheila Young explained on March 27. 2004, when she was recorded while speaking to other medical providers on "Infusion Management" at an INN "sponsored" seminar at the Wyndham Carmel Valley Ranch, in Carmel, California, her clinic had decided to go 100% with Aranesp in the future – on a monthly dosing plan marketed by Defendants:

> About two months ago we were 50/50 Procrit/Aranesp, since we've been with INN and we've got the Group Purchasing Organization [agreement], *Amgen's been very aggressive and right now the doctors made the financial decision that any new starts will be on Aranesp*. . . . Our protocol is pretty simple, we start everybody on 60 micrograms every other week, if they weigh over 180[4] lbs we put them on 100 micrograms every other week. What we do traditionally, what we've done is, using the 90 day rolling

[4] According to the National Center for Health Statistics, the average weight for an adult male in the United States is 189.8 pounds.

> average we never hold, we never hold drug through 90 day rolling [period] and extend the dosing, so if they are every two weeks what we will do is give them the dose and have them come back every three weeks. *Now what we are doing 'cause we've done it a couple of times and we've seen some data from Amgen, what we are going to do is, we're gonna try and get everybody to once a month. So essentially for every target what we are going to do is double their dose and have them come back once a month, so that was a real leap of faith on the doctors' part*, but I don't know about that, but there is some data and there have been some studies which show that that's a good way of doing it." (Emphases added).

244. MANA also received a "special" contract from Amgen and INN that offered larger discounts and rebates than were provided to any other account, and which was to remain a secret contract so that the same terms would not have to be offered to other INN members.

245. In 2004, MANA purchased approximately $1.8 million of Aranesp through INN.

246. These facts support that MANA's medical judgment was supplanted by Defendants' aggressive marketing tactics, which encouraged MANA to submit claims for off-label uses of Aranesp (e.g., dosing epo naïve patients every other week and monthly dosing) and pushed MANA to prescribe large amounts of Aranesp based on Defendants' presentations on the "economics" of Aranesp.

247. As a result of Defendants' actions, MANA submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

6. Nephrology Associates of Birmingham

248. In April 2004, an INN representative contacted ASD Healthcare to obtain the records relating to Aranesp purchases made by Nephrology Associates of Birmingham ("NA-Birmingham"). The INN representative explained that NA-Birmingham was "a big Procrit account" and that he wanted to see if they had started ordering Aranesp. ASD Healthcare

provided the information about NA-Birmingham's purchases, which the INN representative forwarded to the Amgen PSR, Kelly Carter.

249. Shortly thereafter, Mr. Carter sought INN's assistance in performing a "financial analysis" for NA-Birmingham to show discounts and rebates if their patients were switched over to Aranesp. Although NA-Birmingham had already increased Aranesp purchases by that time, Mr. Carter thought that "it would be timely to indicate the $$$ being left on the table."

250. Instead of expressing any concern that Amgen, INN and ASD Healthcare were exchanging information about a potential customer's orders and discussing "economics" of the customer's contracts, the Amgen District Manager thanked the INN representative and Amgen PSR for "all the teamwork around this account."

7. Nephrology Associates of Mobile

251. In February 2004, Nephrology Associates of Mobile ("NA-Mobile") was considering beginning an "anemia management program" and asked Amgen Aranesp PSR Kelly Carter to provide specific information on the economics of Aranesp versus Procrit, including a "spread sheet" of how Medicare reimbursement for the drugs would work, including the "overfill bonus." Mr. Carter discussed the request with an INN representative and Amgen District Manager, Louis Deppe.

252. Thereafter, "special" pricing provided to NA-Mobile by Defendants led Dr. Mazey from NA-Mobile to declare "why don't all Procrit users take advantage of this pricing?"

253. NA-Mobile's orders of Aranesp increased in April 2004, as a direct result of Defendants' marketing efforts, including overfill analysis and "special" concessions.

254. As a result of Defendants' actions, NA-Mobile submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

8. Portland Hypertension & Nephrology

255. Amgen sales representative Jarrett Gross demonstrated to the Portland Hypertension & Nephrology ("PH&N") staff how to extract Aranesp from dead space syringes and how to administer the medication, including overfill.

256. According to the PH&N Lead Medical Assistant, Amgen told them about the overfill contained in the Aranesp vials so that their staff would know that their patients would be administered the labeled dose plus overfill, rather than only the labeled dose amount.

257. PH&N submitted claims for reimbursement from Government Healthcare Programs that included Aranesp overfill.

258. Amgen's encouragement of PH&N to administer Aranesp overfill to patients who would otherwise have received the labeled dosage amount caused PH&N to submit claims for Aranesp dosing that was not medically necessary.

259. Moreover, Amgen's encouragement of PH&N to bill for all Aranesp overfill encouraged (and caused) the submission of false claims by PH&N that overstated the amount of Aranesp dosed.

260. As a result of Defendants' actions, PH&N submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

9. Renal Associates of Grand Rapids

261. The account of Renal Associates of Grand Rapids ("RAGR") received attention from high levels within Amgen, when the account went with Procrit for 2005 because of Procrit's overfill.

262. To convert the account, Syd Stevens (a friend of Amgen) encouraged RAGR's Renal Billing Specialist, Karie Hilley, to consider advantages of Aranesp monthly dosing, as well as that Aranesp had overfill if RAGR wanted to use it. This communication was shared with Ray Chow, Chris Coates, Terry Carney, and Lauren Hirsch.

263. In addition, an Amgen PSR, Ms. Bender, spoke with Ms. Hilley in October 2005 about a practice that billed for Aranesp overfill.

264. As a result of Defendants' actions, RAGR submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

10. Renal Associates of San Antonio

265. Senior Amgen executives, including Ray Chow, Lisa Sherman, and Claes Hornstrand, attended a "blitz" for employees of Renal Associates in San Antonio ("RASA") in 2004 at which Keith Woods and Mark Bachleda pitched the economics of how RASA could profit from Aranesp, including through monthly dosing, using a set of presentation slides. The presentation was made despite the fact that Amgen's internal policies purportedly prohibited discussing economics with medical providers.

266. At the end of the presentation, a woman in the audience asked for a copy of the slides and Bachleda told her that he would look into it, but later remarked to a colleague that "he could go to jail" if he had given her a copy of the slides.

267. As a result of Defendants' actions, RASA submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

11. Renal Physicians of Montgomery

268. Renal Physicians of Montgomery ("RPM"), in Conroe, Texas, had been purchasing equal amounts of Procrit and Aranesp until one of their representatives was flown out

to and paid to participate in an INN "Ad Board," that was part of the proceedings in March 2004 at the Wyndham Carmel Valley Ranch, Carmel. After the "Ad Board" junket, the RPM representative declared that her medical practice would purchase 100% Aranesp in the future because of the Ad Board.

269. Defendants' provision of the Ad Board to RPM caused RPM to purchase Aranesp.

270. As a result of Defendants' actions, RPM submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

12. San Antonio Kidney Disease Center

271. Dan Smitley, R.N., the one time director of clinical services at the San Antonio Kidney Disease Center, which was an account that was targeted by Amgen and INN.

272. The targeting worked: Mr. Smitley became an INN sales representative and the center made significant profits from Aranesp.

273. Mr. Smitley gave a presentation at an INN conference on anemia held at the St. Regis Hotel in Los Angeles, California, in December 2003. During the presentation he answered a question from the audience on how much money his practice made on Aranesp in the previous year. An audiotape of the meeting reveals the following exchange:

> [Q]: You're buying a million dollars of drug each year in your practice, is that right?
> [DS]: We bought, this year, it's about 1.3, 1.4 million.
> [Q]: What kind of profit are you making off that?
> [DS]: Not charging nurse visits 'cause that's a whole separate fee on top of that and everything, just based on the drug alone?
> [Q]: Right.
> [DS]: This year our numbers were about $350,000.

274. Mr. Smitley further explained that this profit margin of about 25% on Aranesp purchases was based on aggressive dosing of Aranesp, that Mr. Smitley referred to as "really industrial dosing":

> Most of our patients are anywhere from 120 to 200 mic[rogram]s . . . I mean we are starting *some really industrial dosing*, one of our physicians just had me last week a 300, sorry two weeks ago, the 300 mic[rogram]s he wants to get me further out, so we start with a much higher dose.

275. As a result of Defendants' actions, San Antonio Kidney Center submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

13. Southwest Kidney Institute

276. Amgen senior management was well aware that INN was presenting economic analyses that included overfill revenues to medical providers. By example, an overview and analysis of the Southwest Kidney Institute ("SKI"), with multiple locations in Phoenix, Arizona, maintained in the files of Vice President of Sales, Leslie Mirani, and prepared by a member of the Amgen sales force stated:

> INN has aggressively targeted this hospital. They have presented a contract to contract numbers comparison, *overfill analysis*, Aranesp in dialysis, and potential of ordering through different tax identification numbers to maximize both Ortho's and Amgen's contract. SKI is aware that top Amgen accounts get an additional 4% rebate in their P3 [purchase agreement] – and they do not. (Emphasis added.)

277. As a result of Defendants' actions, SKI submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

14. Terence Cardinal Cooke Health Care Center ("TCC"), New York, New York

278. In 2005, the Amgen sales representative advised the Administrator and the Quality Assurance Nurse for the TCC End Stage Renal Disease Clinic that Aranesp vials contained overfill

amounts above the labeled dosages. She further advised that TCC could capture an extra 15% of Aranesp and bill third-party payors for this free product.

279. In that year TCC employees administered Aranesp overfill amounts to TCC patients. At the direction of Amgen representatives, TCC billed third-party payors, including the New York State Medicaid Program and the Medicare program, for Aranesp overfill. TCC billed the Medicaid program for 15% more than each Aranesp vial's labeled dosage. Between June 15, 2005 and March 28, 2008, TCC made at least 3,445 separate and false reimbursement claims for overfill and received at least $1,290,000 from the New York Medicaid Program.

280. As a result of Defendants' actions, TCC submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

15. Nephrology Associates of Syracuse ("NAS"), Syracuse, New York

281. In 2004, NAS purchased Aranesp exclusive to any other ESA. It was one of Amgen's top twenty Aranesp accounts. In that year the Amgen sales representative informed the Chief Operating Officer that Amgen could no longer discount its Aranesp single dose syringes. However, the sales representative explained that instead NAS could receive "discounts" by purchasing Aranesp in single dose vials containing free product which NAS could bill to third-party payors.

282. NAS began purchasing Aranesp in vials, rather than in pre-filled syringes, and administered the overfill. NAS administered extra Aranesp to its patients in order to profit by billing for that extra product, not because patients required the additional medication. At Amgen's direction, NAS billed for the overfill at 10% above each labeled fill dose of Aranesp to Medicare and Medicaid. Between February 17, 2004 and January 9, 2008, NAS made at least 690 separate and false reimbursement claims for overfill and received at least $81,500 from the New York Medicaid Program.

283. As a result of Defendants' actions, NAS submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

16. Nephrology Associates of Western New York ("NAWNY"), Amherst, New York

284. During 2005 an Amgen sales representative advised the NAWNY billing clerk that Aranesp vials contained overfill amounts above the labeled dosages. He further advised them that NAWNY could capture the overfill and bill third-party payors for this free product, although he admitted he was not supposed to tell her this. The sales representative enlisted the help of a NAS nurse practitioner and made several presentations on this theme and how to bill for overfill

285. At the direction of Amgen's sales representative, NAWNY billed third-party payors, including Medicare and the New York State Medicaid Program, for 10% overfill over each Aranesp labeled dose. Between April 19, 2005 and August 21, 2006, NAWNY made at least 52 separate and false reimbursement claims for overfill and received at least $2,420 from the New York Medicaid Program.

286. As a result of Defendants' actions, NAWNY submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

17. Winthrop University Hospital ("Winthrop"), Mineola, New York

287. In 2006, Amgen employees, including District Manager Eric Hedge, offered free Aranesp product, in the form of overfill, to induce Winthrop to purchase and administer Aranesp. Winthrop switched from Epogen to Aranesp and began to administer and bill for Aranesp overfill.

288. The Clinic Administrator for Winthrop reported that 10% overfill was administered to the patients and billed to New York Medicaid and the Medicare programs. She also reported that Winthrop created a dosing protocol for Aranesp that included the overfill amounts in the physician's orders. Therefore, a physician would order that 110 micrograms be administered to a patient, so as to capture the 10% overfill. Between March 3, 2006 and December 28, 2008, Winthrop made at least

179 separate and false reimbursement claims for overfill and received at least $30,000 from the New York Medicaid Program.

289. As a result of Defendants' actions, Winthrop submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

18. North Shore University Hospital ("North Shore"), Manhasset, New York

290. Amgen employees, including District Manager Eric Hedge, offered free Aranesp, in the form of overfill, to induce North Shore to purchase and administer Aranesp. North Shore switched from Epogen to Aranesp and began to administer and bill for Aranesp overfill.

291. Subsequently North Shore billed third-party payors, including the New York State Medicaid Program, for the free product it received from Amgen, in the amount of 20% over each Aranesp labeled dose. Between September 5, 2005 and December 12, 2008, North Shore made at least 131 separate and false reimbursement claims for overfill and received at least $13,000 from the New York Medicaid Program.

292. As a result of Defendants' actions, North Shore submitted false and fraudulent claims for reimbursement to Medicare and Medicaid.

F. Defendants Knew Their Conduct Caused False Claims

293. Defendants were aware that their conduct caused Medical Providers to submit false claims.

294. Amgen's internal guidance on the Anti-Kickback Statute and FCA provides:

> For example, if a drug company or its representative helps or encourages a Healthcare Professional to submit a false claim to Medicare perhaps by suggesting that a physician bill for a free sample, the drug company and the representative can be held liable for the Healthcare Provider's false claim. Similarly, if a Healthcare Professional submits a claim that violates another federal law, such as the Anti-Kickback Law, then the

> whistleblower can file a False Claims Act claim based on the violation of the other law.

295. With respect to Aranesp overfill, Defendants did suggest that many physicians bill Medicare for false claims that were medically unnecessary, for services not actually rendered, and tainted by kickbacks.

296. Moreover, there is evidence that Defendants' encouragement of submission of false claims relating to overfill was directly contrary to what Defendants knew the law required. For example, in a May 2005 interview with reporter Chris Rowland of the *Boston Globe*, Amgen Vice President Helen Torley stated that her response to his question "did Amgen promote the use of overfill?" was, "I replied that we did not and explained [the] USP requirement that there be a small amount of overfill to assure [the] labeled amount can be withdrawn."

297. The transcript of Ms. Torley's interview supports her summary. In response to the question, "What is Amgen's position on the marketing of overfill?" Ms. Torley responded (falsely):

> Amgen does not discuss overfill in any way in any of our practices. As you're probably familiar, this is a United States Pharmaco[peia] requirement, that all pharmaceutical products are put in vials and specifically the Epogen vials need to have an excess volume so that it's sufficient to permit people to withdraw their full labeled volume. To me, this requirement in the Epogen 1 ml vial, for example is actually 1.11 mil, but Amgen does not discuss that or promote the use of overfill. It's simply a requirement to assure people can withdraw the right amount of labeled Epogen.

Ms. Torley added that Amgen did not comment on a Centers for Disease Controls' guideline on overfill, either, saying "We view that simply as a manufacturing requirement."

AMGEN'S CONSPIRACY WITH INN, AND ASD HEALTHCARE, TO OFFER KICKBACKS TO MEDICAL PROVIDERS

298. As part of her new position as Aranesp Product Manager in the marketing department in March 2004, Relator was assigned responsibility for Amgen's relationship with Defendant INN (a Group Purchasing Organization), which Relator had been led to believe was an independent entity that focused on nephrology practices and physicians.

299. The idea to create a purported GPO for nephrology came up in a discussion between George Esgro (Amgen's Anemia Sales, National Sales Director) and Scott Carmer (Amgen Aranesp Marketing Director) in early 2003. Both men had seen the success of IPN's International Oncology Network ("ION") in increasing Aranesp sales and resolved to create the International Nephrology Network ("INN").

300. By September 2003 INN was an operative new subsidiary of IPN, and Anthony Corrao left Amgen to become Vice President of the new company. As noted above, in 2002, Defendant ABC had acquired a 20% interest in IPN, INN's parent company and by 2004 wholly owned IPN.[5]

301. After Relator's promotion, she became privy to certain information and documentation that INN was not actually an independent GPO, but rather, was an entity that essentially functioned as a *de facto* marketing arm for Amgen, one that customers/members would see as neutral and objective as compared to Amgen (who was pushing Aranesp) or J&J/Ortho who was pushing Procrit.

[5] In 2002, Defendant ABC paid $5 million for a 20% interest, at that time giving IPN a nominal value of $25 million. In April of 2003 ABC purchased a further 40% for $24.7 million (valuing IPN at $61.75 million). ABC completed the acquisition of the remaining 40% of IPN in April 2004 for $30.9 million (valuing IPN at $77.25 million).

302. Meanwhile, Amgen funneled business to Defendants INN and ASD instead of other Aranesp distributors, INN targeted clinics to convert them to Aranesp, and INN and ASD used the administrative fee as a covert way to pass through additional discounts to customers (price concessions that should have been included in ASP calculations by Amgen).

303. In essence, INN's role was to do the things Amgen could not do and seemingly comply with the Anti-Kickback Statute because INN, as a GPO, purportedly enjoyed a "safe harbor" under the Anti-Kickback Statute, and to pass on price concessions under the guise of "bona fide" fees for purposes of Amgen's ASP calculations and submissions to CMS (*see* 42 C.F.R. § 414.802).

304. Specifically, Relator learned that INN shared highly confidential information with Amgen concerning INN's business operations, including detailed information regarding certain nephrologists and nephrology practices, their revenues, finances, prescribing patterns, and how many "untreated" chronic kidney disease patients an office had.

305. In turn, Amgen provided INN with "target lists" that included the names and addresses of its nephrology customers that both purchased Aranesp and/or purchased competing drugs.

306. Basically, Defendants Amgen and INN would trade any and all information back and forth that would help either or both of them get more business. For example, in an e-mail to Chris Coates of Amgen dated February 9, 2005, Gary Inglese, Director of INN, reported that the San Antonio Kidney Disease Center of San Antonio, Texas, was "finishing up a meeting with Ortho Biotech at this moment and sources tell me they are going to commit to 100% Procrit effect with Q2 due to promises of more favorable reimbursement. They did about 1.8M in

Aranesp in 2004. Looking to do extended dosing. Local Amgen rep has been notified. . . . My full report of endangered and lost accounts will be with you on Thursday."

307. At the same time, wholesaler Defendant ASD Healthcare was knowingly helping Amgen and INN get customers, and vice versa.

308. For example, an ASD representative on an account would "buddy up" with an Amgen PSR and tell him or her that ASD Healthcare would give an important customer a better price on Aranesp. The Amgen representative would then use various means and spreadsheets to let that important customer know that if they switched to ASD Healthcare, they would get a better price on Aranesp or some other medication (as a prelude to convincing the customer to switch to Aranesp).

309. The accounts targeted by Defendants included customers who were using Procrit (purchased from either ASD Healthcare or another supplier) whom the INN and Amgen representatives wanted to convert to using Aranesp or customers who were already using Aranesp but buying it from somewhere other than ASD Healthcare, as well as providers who could influence other providers to deal with Defendants. On occasion, ASD Healthcare would even offer a customer a slight discount on Procrit just to lure them to become a customer of ASD Healthcare, with the main objective being to then convert the account to purchasing Aranesp from ASD Healthcare.

310. Defendant ASD Healthcare also used Aranesp as a "loss leader" for getting the business it really wanted – oncology drugs. As one ASD Healthcare employee told Relator, the pricing he quoted to potential customers was based on how important the customer was to Amgen.

311. "Special" pricing, rebates, and discounts were also made available to certain customers by INN.

312. Basically, the Defendants were triangulating customers: ASD Healthcare, Amgen and INN were all targeting the customer from slightly different angles and the customer often had no idea that the different representatives were talking to each other and sharing information about the customer's business and product orders, or that each company was attempting to direct business to the other(s).

313. Relator also learned that Amgen was funneling large amounts of money to INN ostensibly identified as "administrative fees," when in fact the money was being used for purposes beyond INN's true operating costs as a GPO; rather, the fees were being used, e.g., to arrange and subsidize all expenses paid "retreats" or "educational seminars" for "targeted" physicians (the names of which Amgen provided to INN), to provide extra discounts to customers/target accounts; and to perform practice assessments of INN members and others. These target accounts were high dollar volume accounts and/or accounts that had important political ties to influential nephrology associations in the country that have ties to the government and setting the reimbursement rate for Amgen drugs.

314. INN marketed and led the programs like they were INN meetings, but in fact, all funding came from Amgen. At these "retreats" and "educational seminars," INN and Amgen representatives would lead "informational" sessions that placed heavy emphasis on Aranesp, to the exclusion of any competing drugs, and which placed heavy emphasis on the economic benefit that the physicians could realize if they purchased and administered Aranesp instead of competing drugs.

315. The original deal struck between Amgen and INN, which began on September 15, 2003, paid INN a fixed "administrative fee" of 3% of all sales made through INN to its members. INN used this income, at its discretion, to induce or reward purchasers depending on their size or importance to Amgen.

316. This "administrative fee" was restructured effective April 1, 2004, to include only a 1% fixed fee and the remaining 2% based on performance. The change in the administrative fee meant that INN would have to earn the 2% performance-related fee by demonstrable results.

317. The restructured administrative fee arrangement would prove untenable because a performance-related fee hampered INN's discretion to award kickbacks to customers, provided INN with an uncertain income stream, and jeopardized the 1% pass through from INN to ASD Healthcare, which affected the "bottom line."

318. Once the effect of the restructured administrative fee became evident, ASD Healthcare joined the debate in an attempt to revert the INN administrative fee structure back to the original 3% fixed fee under which INN was not accountable for its performance.

319. The proposal to revert back to the original administrative fee structure was to be put before the Amgen Pricing Committee in the form of a PowerPoint presentation, "The Admin Fee.ppt," prepared by Anthony Corrao and Gary Inglese of INN. This PowerPoint presentation was circulated by e-mail from Corrao to George Esgro, Relator, and Kevin Carlin (Amgen's Anemia Sales Ops/Plan, Senior Manager), on July 21, 2004, "to communicate the high sense of urgency regarding INN's request to reinstate our fixed admin fee back to 3%." According to the e-mail "[t]he executive team at ASD, has informed us, without the reinstatement, they will be raising their off invoice pricing for Aranesp to INN members and reducing the extended dating terms as well."

320. The PowerPoint presentation proclaimed that the administrative fee was set up to "provide for oversight and management of the INN GPO." Under "key points" the presentation acknowledged that "[i]nitially, 3% total of Aranesp sales go through the GPO paid to INN quarterly" and "INN passed through 1% of the sales to ASD the preferred vendor."

321. In case it was not absolutely clear why one third of INN's income as a GPO was being passed along to a for-profit entity such as ASD Healthcare, the PowerPoint presentation explained that "ASD will not be able to run their business at a 13 basis-point margin, which is essentially a break even proposition. No business can do this and thrive. Therefore, to make ASD a viable partner, INN passes through a percentage of its GPO admin fee to ASD." The remaining administrative fee (net of ASD's fee) "provides INN with 2% for operations, to deploy a sales and practice management team of 8, to target Procrit loyal customers."

322. This presentation made INN's status as a contract sales force for Amgen absolutely plain. The proposal even went so far as to suggest that "[i]f the Admin fee is increased beyond 3%, INN would pass through additional discount directly to its Aranesp GPO customers."

323. The slide deck also reported Defendant ASD Healthcare's position: "ASD maintains that failure to increase the admin fee will force them to raise their pricing, and that in turn will have devastating consequences to the INN/ASD competitive advantage for its customers." Thus, just a few months after ABC purchased outright ownership of INN, another of ABC's wholly-owned subsidiaries (ASD Healthcare) was negotiating INN's administrative fee: first through ASD Healthcare in the form of a 1% pass through; and second, in the form of a guaranteed income to INN.

324. By August 5, 2004, Hani Sefain, Amgen Associate Director of Contracting and Pricing, had become involved in the wrangling over the INN administrative fee. Mr. Sefain forwarded a revised draft contract regarding the fixed 3% administrative fee to Relator, Fred Manak, Amgen's Director of Corporate Pricing, and Ryan Bradley, Amgen's Contract Pricing and Marketing Manager. Mr. Sefain informed them that he was scheduled to discuss the administrative fee issue with Helen Torley, VP of the Amgen Anemia Business Unit.

325. Dave Auzat, Amgen Senior Operations Manager, Corporate Pricing Operations, and Fred Manak made the case for the administrative fee reversion to Amgen's Pricing and Contracting Committee and succeeded. By August 13, 2004, Mr. Sefain circulated an updated INN contract reverting back to the old fee structure, and the fixed fee was reinstated effective August 15, 2004.

326. By January 2005, Ryan Bradley of Amgen was turning his mind again to the INN administrative fee structure. In an e-mail of January 14, 2005, he raised the issue with Daniel Brox, Amgen Senior Manager of Aranesp Value Team, reminding Brox that "the intent was to initiate a performance-based admin fee." Brox countered with a proposal for the administrative fee that would "give them [INN] more upside opportunity while also putting some of their current fees at risk." Clearly the legality of the scheme was foremost in Brox's mind because he asked Ray Chow, Amgen Director of Aranesp Marketing: "If we put some fees at risk, do you think JW [a reference to in-house counsel] will go for it?"

327. According to an Amgen PowerPoint presentation, "INN admin fee", dated February 2, 2005, INN was worth every penny spent by Amgen. According to the Amgen analysis, increased sales directly attributable to INN's efforts between April and November 2004 equaled $980,000, and during that period Amgen paid INN $447,000 in "admin fees," giving

Amgen a 119% return on investment on fees paid to INN. INN started strongly in September 2003, and continued that way; it is now the country's largest GPO selling pharmaceuticals to medical providers and physicians specializing in nephrology.

328. Amgen's direction of the business of specific accounts to INN, and INN's targeting and conversion of those accounts to Aranesp, has cost the government millions of dollars in part because the majority of the relevant patients receive Medicare and/or Medicaid benefits and Aranesp had a higher reimbursement rate than Procrit (at times, Aranesp also had a higher reimbursement rate than Epogen).

329. At about the same time as the negotiation of the administrative fee took place, Relator also learned that INN representatives were not disclosing INN's direct relationship with Amgen to its customers, and instead were conveying the impression that INN was a wholly independent organization, with no affiliation with or ties to Amgen.

330. In fact, INN was not independent of Amgen, and functioned as a marketing arm of Amgen, engaging in practices on Amgen's behalf that Amgen fully supported and condoned, but could not legally do in its own name.

331. As part of these efforts, INN representatives would go into doctor's offices and meet with doctors, billing managers, office managers, etc., ostensibly to help them find billing errors or ways to increase reimbursement and revenue, or to offer or promote ancillary services that would improve office efficiency and economics.

332. As part of the conspiracy with Amgen, INN would audit target medical offices or clinics and, under the pretense of acting as an independent GPO, prepare "Practice Assessment" forms providing management advice. Unbeknownst to the target customer, INN would share the

results with Amgen and the Defendants would then formulate a plan about how to entice the clinic switch to Aranesp.

333. For example, two practice assessments done in late 2003, reveal the following information:

(a) On December 8, 2003, INN prepared a practice assessment ostensibly for the benefit of the Balboa Nephrology Medical Group of San Diego, California. According to the assessment which INN provided to Amgen, this 19 physician group served patients 65% of whose principal healthcare insurer was Medicare. A side report that INN prepared for Amgen noted that there was an "immediate opportunity" to "[e]xpand [the] CKD program and shift to Aranesp." Chris Coates, former Amgen District Manager and current Nephrology Business Unit Director of Corporate Accounts, reported to Relator that this practice had never before considered capturing the overfill but had resolved to do so after speaking with Defendants;

(b) On October 30, 2003, INN prepared a practice assessment ostensibly for the benefit of the Rockland Renal Associates of West Nyack. According to the assessment which was provided to Amgen, this five-physician practice served patients 65% of whose principal healthcare insurer was Medicare. However, of the 400 ESA prescriptions written per month at the time of the report, 100% were for Procrit. According to an internal Amgen document tracking INN's progress in converting target practices, twelve months later, Rockland Renal had been converted by Defendants and spent $231,240.00 on Aranesp in the month of October 2004;

(c) A physician affiliated with Rockland Renal Associates of Nyack, New York, confirmed that INN prepared a practice assessment for his nephrology practice. The

physician was surprised, however, that INN would have shared that practice assessment with Amgen. He stated that INN represented itself as a separate entity operating at arm's length from Amgen. Rockland Renal Associates was not a member of INN at the time the practice assessment was conducted; and

(d) A physician associated with Rockland Renal Associates also reported participating in a dinner meeting with an Amgen sales representative and INN sales representative before his practice converted from Procrit to Aranesp in 2004. He stated that at one point during the dinner, the Amgen sales representative left the table and the comment was made that the INN and Amgen sales representatives "can't talk in front of each other." INN and Amgen won the Rockland Renal Associates account, and Rockland Renal was a $1.2 million dollar account for Amgen.

334. INN shared its practice assessments with Amgen to give Amgen a competitive advantage in trying to undercut Procrit pricing and to provide the Amgen sales force with an understanding of the practice's financials and dynamics. This in turn increased INN's earnings under the administrative fee provision.

335. INN representatives were aggressive in other ways, as well. For example, INN representative Shelley Huttar wrote to a doctor that he should not miss the "revenue opportunity" of converting his patients to Aranesp "while it still lasts," and that it "could help pay for [his childrens'] private school [tuition]."

336. In an e-mail of November 4, 2004, Gary Inglese, director of INN, "pitched" "INN's capabilities" to Ray Chow of Amgen, explaining "we will build or design a program to look like what you want it to look like." Among other things, Inglese included a sample of a practice assessment adding "[t]hese require 2 days on site to gather data and interview. We can tailor to specific issues if you want to zero in on something specific. The price per assessment is

$30,000.00 each." In an e-mail of November 26, 2004, Gary Inglese sent Ray Chow a "Conversion Account Spreadsheet" showing three things purporting to justify INN's value for money to Amgen:

1. Conversion influence from Procrit® to Aranesp®

2. Growth influence of Aranesp® market share

3. Retention of the accounts from going over to Procrit®

337. A document entitled "INN Growth Report," also attached to the e-mail, showed that INN had added 1086 new doctors to its membership between January 2004 and October 15, 2004, and that sales of Aranesp to those new members grew from $901,684 in January 2004 to $4,343,055 in September 2004. Inglese was upbeat about INN's progress, "We continue to see positive, upward growth. The intangible items (the things one cannot quantify) remain the relationships we are building and have formed with over 348 practices. And we appreciate and value our relationship with each of you."

338. In a subsequent proposal that Inglese sent to Chow on February 10, 2005, Inglese expounded on the services INN could sell to Amgen:

(a) "Saturday Symposia" with Focus Groups for nephrologists and office managers. Inglese proposed that "Amgen may compile *a target list of nephrologists to be recruited by INN*." (emphasis added); and

(b) "Practice Assessments," Inglese explained, "This initiative will look at the top 20 Amgen accounts or targets and assemble the collected data into a unified and comprehensive database." This would allow INN "[t]o access a practice where 'pharma' cannot go" through an "intimate look inside a practice." This "intimate look" would reveal "Practice Financials; AR, aging reports, AP; Income sharing; Overhead allocation

method; Revenue sharing; Patient payment policy; Adjustments and write offs; Collections; Billing (in house or out sourced); Performance metrics; Bonus structure; and Revenue sharing models" all for $30,000 per practice.

339. A February 13, 2004 e-mail from Eric Price, Aranesp Team Product Manager before Relator took over the position, set out the cost of some of the services that INN performed for Amgen in 2003 and the proposed budget for 2004 (the reckoning did not include charges for practice assessments):

Summary of costs:

Total INN Costs

	2003	***2004***	***Program Total***
Regional Advisory Board Meetings	$948,000	$709,499	$1,657,499
Practice Level Advisory Board Meetings	$732,400	$720,016	$1,452,416
INN 2004 Standards Development Retreats		$56,250	$56,250
INN 2004 Nephrology Nurse Dinners		$148,800	$148,800
INN 2004 Communications Initiatives		$82,500	$82,500
INN 2004 Newsletters and Market Research Surveys		$17,500	$17,500
Total INN Costs	$1,680,400	$1,734,565	$3,414,965
Total estimated honoraria	$264,000	$178,000	$442,000
Total cost	$1,944,400	$1,912,565	$3,856,965
	budget	$1,800,000	
	current spend	$1,734,565	
	remainder	$65,435	

340. Amgen employees and INN representatives would also perform "chart audits" of patient records/charts in offices and clinics in an attempt to find additional patients who might be "candidates" for Aranesp.

341. In addition to the conduct alleged above which provided illegal inducements or kickbacks to promote the sale of Aranesp, during the time that Relator worked for Defendant Amgen, she was also exposed to, and/or required to participate in, various other types of kickback activity, including, without limitation, "seminars" and "retreats" for physicians (and/or their office staff) that were hosted or funded by Amgen and/or INN. These seminars and retreats ostensibly took place to provide neutral, educational information to the attendees – e.g., information concerning various competing drugs, and/or concerning billing practices. In fact, however, the seminars and retreats often were little more than thinly-disguised commercial presentations for Aranesp.

342. The Amgen/INN seminars and retreats typically were held at vacation locations such as Carmel, California (the location of one such event attended by Relator in March 26-27, 2004), with Amgen directly or indirectly paying all the travel, food, and accommodation expenses of the attendees. Furthermore, the physicians and their staff who attended the seminars and retreats typically were paid a so-called "honorarium" of anywhere from $500 to $3,000 – such amounts being paid even in cases where an attendee did not make a speech or otherwise make a presentation. Amgen footed the bill for these expensive seminars and retreats – and paid sizeable "honoraria" to the attendees – all with the express and knowing intention of inducing, and/or rewarding, the attendees for prescribing Aranesp.

343. Amgen also used the aforementioned seminars and retreats as a means of recruiting the office administrators/managers/billers of physicians or physician groups. In particular, Amgen encouraged office administrators/managers/billers who had attended an Amgen seminar/retreat, or who came from offices with a good track record of writing Aranesp prescriptions, to contact their counterparts at other physician offices in order to tout the financial

benefits of prescribing Aranesp. Such secondary contacts sometimes were referred to as "reimbursement roundtables," and the individuals who arranged and performed these contacts were paid an additional "honorarium" of $250 to $1,500 for doing so.

344. Amgen's internal documents show, and Relator knows from firsthand experience, that Amgen had several programs for so-called "medical education" including without limitation, speaker programs, educational grants/fellowships, advisory boards, focus groups, consulting services and preceptorships, all in conjunction with INN. Some nephrologists received substantial amounts of money from Amgen, with INN's knowledge, to be "consultants"; in fact, they did little if any consulting work, and the payments were in reality tied to their continued practice of writing substantial volumes of Aranesp prescriptions.

345. By way of further example, Relator offers the following information about Defendants' activities in promoting the sale of Aranesp:

(a) Relator has notes of several meetings or conversations where representatives of Amgen, INN, and/or ASD Healthcare discussed the overfill in Aranesp single use vials; how that overfill compared to the overfill in multi-dose Procrit vials and to the overfill in Aranesp PFS; marketing and billing of the Aranesp overfill; and customers' reactions to this marketing. Among her notes are records involving such communications on July 19, 2004 (attended by Gary Inglese, Helen Torley, George Esgro, Bob Azelby, Kevin Carlin and Relator); October 4 and 8, 2004; and November 12, 2004;

(b) Relator has notes of a conversation with INN (Inglese) on October 4, 2004, in which she noted "Amgen funds practice assessments to gain info on customers and get ASP message out . . . Gary is constantly hearing offices 'want an objective

opinion,' not 'Amgen or Ortho.'" For this same reason, Inglese by e-mail on June 28, 2004, told Relator he did not want her to accompany him on an upcoming practice assessment to a provider who was a "50/50 account and I think they would be hesitant to being open to me with anyone else there;"

(c) Relator has notes of numerous meetings in 2004-2005 which she attended or conversations she was part of where representatives of Amgen (e.g., Chow, Esgro, Azelby, Carlin, and Torley) and/or INN (Inglese and Corrao) discussed changing the INN administrative fee and the purpose or use to be made of the fee. From these meetings, as well as other evidence, it is apparent that Defendants were using the INN administrative fee to fund additional discounts of between at least 1-3% to be passed through to certain customers (through INN and/or ASD Healthcare) to obtain or retain the customers' business, as well as to enable INN to fund medical education programs and the other activities detailed herein. In Relator's notes of such conversations, there are also references to assertions that INN was in a "safe harbor" but Amgen was not. Among Relator's notes are notes of meetings on: June 21, 24, 25-28, and July 19 and 21, 2004; and

(d) An August 2004 PowerPoint presentation prepared by Joyce Tao at Amgen titled "Retrospective Analysis of Aranesp Contracts and Considerations for Future Contracting Decisions," contains a slide that reads: "Administration fees filtered through as discounts may not be included in ASP." Relator and numerous others (including Victoria Goldin, another Amgen marketing manager) received copies of this presentation. The presentation was made at an Amgen meeting.

346. In addition, an e-mail from Frank Messana of Amgen on November 3, 2004, to Chuck Halstenson, Executive Director of the National Renal Administrators Association, states: "Admin fees are used to pass back to customers, but they are all over the board, from 0 to over 3% depending on the customer size and importance, I guess."

347. On March 2, 2005, Relator attended a meeting with, among others, IPN/INN, Amgen and US Bioservices (another subsidiary of ABC). These corporations were represented by the following individuals: Barry Sandler, Anthony Corrao, David Gilardi, and Gary Inglese for IPN/INN; Peter Arkelian, Todd Goldberg, Matt Skelton, Bonnie Morgan, Sam McDade, and Bob Goria for Amgen; and Joe Paglisi, President of US Bioservices. At that meeting, US Bioservices made a presentation to Amgen of the services the Amerisource group as a whole could provide to Amgen and portrayed the Amerisource conglomerate as one coordinated, cohesive unit. The ostensible purpose of the meeting was to promote US Bioservices and Imedex to Amgen. (ABC had acquired US Bioservices in 2003 for $160 million and Imedex in May of 2004 for $17 million).

348. All parties were conscious that by January 1, 2005, Medicare Part B reimbursement for Aranesp in the physician clinic setting would be based on the new ASP ("average sales price") formula. US Bioservices was proposing that Amgen should contract with Imedex and US Bioservices to use the companies as channels through which to distribute discounts to customers without having to include those items in ASP data. US Bioservices was to be added as a specialty pharmacy provider for Aranesp and would handle 97% of all retail prescriptions for Aranesp. The proposal was to amend the INN contract to include US Bioservices. The advantage of using the existing INN shell as discussed at the March 2nd meeting was that the increased business would increase the absolute level of the administrative

fee and the increased administrative fee would enable INN to pass discounts to additional customers; whereas Imedex's role would be to take advantage of the imminent ASP change to go on an "educational" blitz and market the economics of Aranesp as well as administering "unrestricted educational grants" to favored clinics.

349. Just as INN was a means by which to funnel discounts to GPO members, so too it was proposed for Amgen to make further strategic alliances with ABC, with the plan that, by disguising these pass-throughs as administrative fees, Amgen need not include those fees in its subsequent ASP data. As noted above, Joyce Tao, a sometime employee of Amgen, had written in an August 2004 PowerPoint presentation, "Retrospective Analysis of Aranesp Contracts and Considerations for Future Contracting Decisions," that "Administration fees filtered through as discounts may not be included in ASP." Relator and others at Amgen received copies of this presentation.

350. Another example is an April 10, 2004 e-mail from Nicole Wilson to INN Director of Sales and Marketing, Gary Inglese. The e-mail concerns a joint meeting that Wilson held with an INN SAM and a physician in Sarasota, Florida. The e-mail states that the INN SAM, presented a financial analysis to the Sarasota physician comparing Procrit and Aranesp prices for vial sizes and Medicare reimbursement differences. The e-mail praises the INN SAM for convincing the physician to join INN on the spot, which required the physician to buy Aranesp through INN, and also states that the INN SAM successfully signed on three other Aranesp accounts totaling $530,000 in sales.

AMGEN MISTATED THE ARANESP ASP TO MEDICARE

351. Amgen's pass through payments to INN and ASD Healthcare, and ultimately ABC, should have been included in Amgen's Average Sales Price ("ASP") calculations for

Aranesp reported to CMS pursuant to 42 CFR § 414.804. Amgen's administrative fee pass through payments to Defendants were not "bona fide service fees," as defined by 42 C.F.R. § 414.802, and should have been included as a price concession, pursuant to 42 C.F.R. § 414.804(a)(2), in calculating the ASP for Aranesp. Amgen's failure to include these payments in its ASP calculations for Aranesp caused the quarterly ASP for Aranesp to be overstated as reported to CMS.

352. Amgen's failure to include these pass through payments in its ASP calculations resulted in its reported ASP for Aranesp being inflated. As a result of Amgen's failure to report these payments as price concessions in ASP calculations, the Government Health Care Programs were harmed as follows: (1) State Medicaid Programs that utilize the ASP reimbursement methodology, which is the mandated reimbursement methodology utilized by the Medicare program beginning in 2005, overpaid for Aranesp claims (including as to any federal funding for payment of those claims); (2) State Medicaid and Federal Medicare Programs overpaid for dually-eligible Medicare/Medicaid beneficiaries; and (3) other Government Health Care Programs, including Medicare, which used the ASP reimbursement methodology (the mandated reimbursement methodology utilized by the Medicare program beginning in 2005), overpaid for Aranesp claims.

353. Amgen also failed to include the value of overfill in the ASP information it reported to CMS, even though, as set forth in this Complaint, Amgen marketed and obtained sales of Aranesp based on the value of the Aranesp overfill and even though, under 42 U.S.C. § 1847A(c)(3), a drug manufacturer is required to take into account various things that reduce the cost of a drug for purposes of the ASP certification to Medicare, including discounts and "free goods that are contingent on any purchase requirement."

354. Defendants knew that the asserted value of the Aranesp overfill was material to the amount that medical providers paid for Aranesp and would affect the sales price data of Aranesp.

355. Among other things, Defendants knew that in the course of an analysis conducted by the HHS OIG to set the reimbursement rate for Epogen as of January 1, 1998, OIG noted that Amgen had provided 25% overfill in Epogen, allegedly so that medical providers could extract full doses of Epogen. (Amgen subsequently reduced the Epogen overfill to 16.8% by 1998).

356. For its analysis of the cost of Epogen, OIG obtained cost report information that included the cost per 1,000 units of Epogen administered, including overfill, from which OIG determined that "the average amount [free-standing dialysis facilities] were able to extract was approximately one half of the 25 percent overfill. *The use of this additional EPO would materially affect each provider's cost*." HHS OIG Office of Inspector General for Health Care Financing Audits, *Review of EPOGEN Reimbursement (A-01-97-000509)* ("1997 OIG Report") at 8 (Nov. 24, 1997) (emphasis added); *id.* at 5. As a result of its review, OIG recommended that the Medicare reimbursement rate for Epogen be lowered from $10.00 per 1,000 units to $9.00 per 1,000 units. *Id.* at 7.

357. Defendants also knew that their customers' receipt of Medicare reimbursements for Aranesp overfill would affect those customers' cost of Aranesp in a material way. Nevertheless, Defendants did not provide information about their promotion of the use and billing of Aranesp overfill to Medicare for purposes of setting the Aranesp ASP.

DEFENDANTS MISTATED THE AMOUNT OF OVERFILL "AVAILABLE" IN ARANESP

358. The analysis conducted by the 1997 OIG Report concluded that, on average, the free-standing dialysis facilities analyzed were able to extract about half of the 25% overfill from Epogen multi-use vials, or 12.5% overfill. *Id.* at 7-8.

359. Part of the OIG's review of Epogen included discussions with the Controller of Gambro (an operator of dialysis facilities) on May 28, 1997, in which he stated a belief that Gambro was able to use approximately 14% of total Epogen overfill of 25%. (Gambro's Controller also validated the OIG's cost analysis that included overfill units in the denominator).

360. With respect to Aranesp, Amgen has claimed that overfill that has varied between 16.8% and 19% is necessary because of manufacturing and other issues.

361. Amgen's justification for the amount of overfill in Aranesp is necessarily based on the premise that one could not, in fact, extract and administer all of the overfill in Aranesp vials.

362. Thus, Defendants understood that it was unlikely – if not physically impossible – for a medical provider consistently to withdraw and administer *all of the overfill* in Aranesp vials.

363. Nevertheless, Defendants marketed Aranesp to medical providers by encouraging them to seek and file Medicare claims for reimbursement for *all of the overfill* in Aranesp vials.

364. Defendants thus encouraged the submission of false and fraudulent claims to Medicare relating to Aranesp that was not paid for by a medical provider and that *was not actually administered to a patient.*

365. Defendants did, in fact, succeed in convincing medical providers to submit such false and fraudulent claims to Medicare, which were reimbursed by Medicare. Claims data

received to date indicates that medical providers throughout the United States who were contacted by Amgen did, in fact, increase their level of Aranesp purchases and submitted fraudulent claims to Medicare and other Government Healthcare Programs.

CLAIMS SUBMITTED AND DAMAGES CAUSED TO GOVERNMENT HEALTH CARE PROGRAMS

366. The Defendants' actions described above have caused the submission of false and fraudulent claims, and they have made and used, and/or caused to be made and used, false records and statements for the purpose of having false and fraudulent claims for Aranesp prescriptions submitted to, paid and/or approved by Government Health Care Programs including Medicare.

367. Among other things, claims filed with the Government Health Care Programs because of Defendants' actions have contained false and fraudulent statements and material omissions.

368. Defendants' actions have also caused medical providers who received Aranesp overfill and/or other benefits as a kickback to violate the conditions of their receipt of Medicare reimbursements, including the certification that they would comply with the Anti-Kickback Statute as a condition for the receipt of Medicare reimbursements.

369. Defendants' actions have also caused medical providers who received Aranesp overfill and/or other benefits as a kickback to file false certifications with Government Health Care Programs, including pursuant to Forms CMS-885, that they were in compliance and/or would comply with the Anti-Kickback Statute.

370. There is evidence that Defendants have caused the majority of medical providers purchasing Aranesp from Amgen to provide false certifications on Forms CMS-855A and CMS-

855I during the time that Defendants were providing Aranesp (with the related overfill kickback) to those medical providers.

371. The Provider Enrollment Chain and Ownership System ("PECOS") is a mandatory national enrollment system administered by CMS that was implemented after Amgen began to market Aranesp. It allows physicians and practice groups to enroll in Medicare or to make a change to their Medicare enrollment information online.

372. Enrollment in PECOS requires a medical provider to recertify compliance with the Anti-Kickback Statute at that time. Specifically, when enrolling in PECOS, a medical provider either must complete the paper Medicare enrollment application and certification by completing the appropriate Form CMS-855A or CMS-855I (including certification of compliance with federal law and the Anti-Kickback Statute), or must complete an online enrollment, followed by submission of a two-page hard copy certification statement that requires the same certification as Form CMS- 855A and CMS-855I.

373. CMS requires all medical providers that receive Medicare reimbursements, and who have not submitted a CMS-855 enrollment form since 2003, to enroll in PECOS through either of the processes described above, both of which require contemporaneous recertification by the medical provider of compliance with federal laws, including the Anti-Kickback Statute.

374. The PECOS registration requirement is mandatory and governing regulations provide that medical providers not enrolled in PECOS will not receive Medicare reimbursements. Although the deadline for the application of that sanction has been extended to January 3, 2011, by 2010, most medical providers had enrolled in PECOS (and, in so doing, had recertified their compliance with federal law, including the Anti-Kickback Statute, as a condition of receiving Medicare reimbursements).

375. Other common circumstances regularly require medical providers to submit Forms CMS-855A or CMS-855I, along with contemporaneous certification of compliance with federal law and the Anti-Kickback Statute. For example, CMS requires the submission of a new CMS-855A enrollment form in the event of an acquisition, merger, or consolidation of a medical practice enrolled in Medicare.

376. Further, in the event of a change of ownership of a practice enrolled in Medicare, the new owner can either submit a new enrollment form (with certification), or assume the obligations of the existing provider agreement through an assignment process. Where an agreement is assigned to the new owner, the new owner specifically assumes the agreement subject to "all applicable statutes and regulations and to the terms and conditions under which it was originally issued." 42 C.F.R. § 498.18.

377. Institutional medical providers must also complete the CMS-855A certification whenever they reactivate a Medicare enrollment, voluntarily terminate a Medicare enrollment, revalidate their Medicare enrollment, or change any of their Medicare information, including: identifying information, practice location information, payment address and medical record storage information, ownership interest and / or managing control information, chain home office information, billing agency information, special requirements for home health agencies, authorized officials, delegated officials, or information about adverse legal actions / convictions.

378. Similarly, physicians and other practitioners must complete a version of Form CMS-855I, including the certification of compliance with federal law including the Anti-Kickback Statute, whenever they do any of the following: change any of their Medicare information, including identifying information, practice location information, payment address and medical record storage information, information about individuals having managing control,

final adverse actions/convictions, and billing agency information. Recertification of compliance is also required when physicians and other practitioners enroll with another fee-for-service contractor, reactivate their Medicare enrollment, voluntarily terminate their Medicare enrollment, or revalidate their Medicare enrollment. Physicians are other practitioners are also required generally to notify the government if any of the certifications or statements on the Form change.

379. As of November 2009, the majority – *i.e.*, on the order of 70% — of all Medicare-eligible medical providers (including physicians and medical practices) had re-enrolled in Medicare since 2003, including for the above reasons.

380. These Medicare reenrollments took place after Amgen began to market Aranesp and to provide kickbacks, including in the form of Aranesp overfill, to medical providers. Any medical provider who received kickbacks from Defendants, including Aranesp overfill, prior to reenrollment in Medicare was caused by Defendants to submit (and did in fact submit) a false certification of compliance with federal law, including the Anti-Kickback Statute, upon reenrollment in Medicare. When the providers signed these reenrollment forms, they knew that they would be accepting kickbacks from the Defendants in violation of the anti-kickback statute. Also, as a result of Defendants' conduct, all Medicare claims, including claims for Aranesp, submitted by those medical providers after such false certification was executed, constituted false claims that Medicare should not and would not have paid.

381. Further, Defendants have marketed Aranesp in a way that has compromised physicians' independent medical judgment and threatened patient safety through the use of kickbacks, including the promotion of "overfill" billing, the passing through of INN administrative fees to customers, and the advisory boards and other inducements offered by Amgen, INN, and ASD Healthcare under the guise of operating as a legitimate GPO.

382. The impact of Defendants' misconduct is all the more profound on Government Health Care Programs, such as Medicare, given that Aranesp is more expensive than alternative therapies. According to an Amgen document dated August 10, 2004, Aranesp was 43% more expensive than Procrit.

383. By Defendant Amgen directing business to Defendants INN and ASD Healthcare, and INN and ASD Healthcare helping Amgen identify and convert target accounts, Government Health Care Programs have been damaged significantly because the majority of the patients who use Aranesp are Medicare or Medicaid beneficiaries.

384. As noted herein, Medicare spends substantial sums annually to reimburse providers for Aranesp, approximately $6 billion from 2003 into 2009 (*see* Table I, *infra*). Amgen recognizes the importance of, *e.g.*, Medicare reimbursement, to its business, and recognizes that it is subject to compliance with various federal and state laws such as the Anti-Kickback Statute. For example, in Amgen's 2008 Annual Report, under the section "Risk Factors" Amgen states: that pursuant to a Decision Memorandum of March 14, 2007,

> CMS issued changes to its Medicare National Coverage Determinations Manual that resulted in the reduced use of ESAs in clinical practice….We [Amgen] believe this restriction on reimbursement of ESAs in the Decision Memorandum has had a material adverse effect on the use, reimbursement and sales of Aranesp®, and our business and results of operations.

Under the section "Other," Amgen states:

> We are also subject to various federal and state laws, as well as foreign laws, pertaining to healthcare 'fraud and abuse,' including Anti-Kickback laws and false claims laws… Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal healthcare programs (including Medicare and

> Medicaid). If the government were to allege against or convict us of violating these laws, there could be a material adverse effect on our business, including our stock price.

385. Payment for Aranesp through Medicare is such an important component in Aranesp sales that Amgen gave the following warning in its 2004 annual report: "The Medicare Prescription Drug, Improvement and Modernization Act (or the 'Medicare Modernization Act' ('MMA')) was enacted into law in December 2003. We expect that, beginning in 2005, reimbursement changes resulting from the MMA are likely, to a degree, to negatively affect product sales of some of our marketed products."

386. Defendants' overfill and other inducements caused medical providers to submit false provider certifications that they were in compliance with the federal and state Anti-Kickback laws.

387. Compliance with the Anti-Kickback laws is a precondition to payment by the Medicare program, and by other Government Health Care Programs. By virtue of Defendants' overfill and other inducements to medical providers, the Medicare program and other Government Health Insurance Programs: (1) reasonably and foreseeably paid medical providers for overfill amounts; (2) reasonably and foreseeably paid medical providers for provider-administered and prescribed Aranesp that they would not have otherwise ordered or prescribed; (3) reasonably and foreseeably paid for renewed and continuing treatments of Aranesp for patients who might not have otherwise received that treatment; and (4) reasonably and foreseeably paid for the more expensive drug, Aranesp, rather than the less costly alternative, Procrit.

388. By way of example, Relator offers the following Tables I through V as evidence of claims submitted and damages caused to the Medicare Program.

(a) **Table I** contains totals of Aranesp claims submitted and paid by Medicare from 2003-part way through 2009;

(b) **Table II** has been compiled from practice assessments prepared by INN and shared with Amgen for strategic purposes, and from purchase data contained in INN tracking reports provided to Amgen. The assessments were done in two parts, a five or six page overview in which INN provided some advice to management and introducing themselves in anodyne terms:

> The International Nephrology Network (INN) is a newly constituted group purchasing, physician services organization specializing in programs, services and products for the nephrology network. INN's focus is in reducing pricing on office-administered pharmaceuticals and medical supplies, regulatory compliance, practice management support and clinical trials opportunities. INN is focusing predominately on large and premier accounts. Membership is free of cost and obligations.

The second two page report was an executive summary for Amgen's benefit including pithy statistics and advice such as "immediate opportunity….switch to Aranesp;"

(c) **Table III** contains purchase and other information gleaned from INN tracking reports provided to Amgen;

(d) **Table IV** shows Medicare Part A and Part B Aranesp claims submitted and reimbursement amounts for Rockland Renal Associates; and

(e) **Table V** shows the success that Defendants had in converting several clinics to using all Aranesp.

TABLE I

MEDICARE TOTALS FOR ARANESP CLAIMS AND DISBURSEMENTS FOR THE YEARS 2003-2009 (partial) (data for 2001 and 2002 not presently available).

	Claims	Disbursements
2003	$1,016,194,767.00	$419,989,693.00
2004	$1,987,718,083.00	$874,886,681.00
2005	$2,837,911,696.00	$1,107,282,522.00
2006	$3,295,890,250.00	$1,190,095,606.00
2007	$3,164,204,214.87	$1,157,163,947.00
2008	$1,974,024,674.91	$654,459,737.00
2009 partial	$413,708,136.54	$147,465,866.00
	$14,689,651,823.00	$5,551,344,052.00

TABLE II

COMPILED FROM PRACTICE ASSESSMENTS PREPARED BY INN AND SHARED WITH AMGEN FOR STRATEGIC PURPOSES, AND FROM PURCHASE DATA CONTAINED IN INN TRACKING REPORTS PROVIDED TO AMGEN.

Practice	**Details**	**Date of Assessment**	**Specialty**	**Medicare Population**	**Purchase**
Balboa Nephrology Medical Group 5353Mission Center Road, Suite 318 San Diego, CA 92108	19 physicians 10 nurses 8 offices	October 30, 2003	Nephrology	65% of the patients have Medicare as their primary insurance.	Spent $696,021.60 on Aranesp between March and August 2004.
Rockland Renal Associates Centerock East - 2 Crosfield Ave, Suite 312 West Nyack, NY 10994	5 physicians	December 8, 2003	Nephrology	65% of the patients have Medicare as their primary insurance.	In October 2004, the practice spent $231,240 on Aranesp.
Central Nephrology Group 5143 Office park	6 physicians, 1 assistant	December 16, 2003	Nephrology	65% of the patients Medicare as their	

Practice	Details	Date of Assessment	Specialty	Medicare Population	Purchase
Drive Bakersfield, CA 93309				primary insurance.	
Zak Maniya, MD Mercerville Professional Park 2333 White-Horse Rd, Suite 4 Hamilton, NJ	2 physicians	November 7, 2003	Primarily nephrology but has a significant portion of internal medicine patients.	50% of the patients have Medicare as their primary insurance.	In July 2004, the practice spent $6790.80 on Aranesp.
Houston Nephrology Group Memorial Professional Building 1 902 Frostwood Suite 166 Houston, Texas	5 physicians, 3 nurses	December 1, 2003	Nephrology	70% of the patients have Medicare as their primary insurance.	Spent $151,699.80 on Aranesp between August 31, 2003 and September 1, 2004.
Nephrology Associates 1584-02 Constitution Blvd Rock Hill, SC 29732	4 physicians, 1 nurse	October 21, 2003	Nephrology but it also has a significant focus on internal medicine patients	67% of the patients have Medicare as their primary insurance.	Spent $38,304.00 on Aranesp between March and August 2004.
Nephrology Hypertension Clinic, PC 1331 Monroe Dearborn, MI 48124	10 physicians with multiple offices	December 1, 2003	Nephrology but it also has a significant focus on internal medicine patients.	90% of the patients have Medicare as their primary insurance.	Spent $113.709.00 on Aranesp between March and August 2004.
Nephrology & Hypertension, PC G1071 N. Ballinger Hwy, Suite 310 Flint, MI 48504	7 physicians with 3 offices	December 1, 2003	Primarily nephrology but the clinic also has a significant portion of internal medicine patients.	90% of the patients have Medicare as their primary insurance.	Spent $57727.20 on Aranesp between March and August 2004.
Nephrology Associates of S. Miami 9193 SW 72nd Street Suite 200	6 physicians	December 23, 2003	Primarily nephrology but it also has a significant portion of	40% of the patients have Medicare as their primary insurance.	Spent $52,192.00 on Aranesp between March and August 2004.

Practice	Details	Date of Assessment	Specialty	Medicare Population	Purchase
Miami, FL 33173			internal medicine patients.		
Nephrology Medical Associates 5525 Etiwanda Ave Suite 305 Tarzana, CA. 91356	5 physicians, one nurse practitioner and 24 staff	October 21, 2003	Primarily nephrology but also a number of internal medicine patients.	60% of the patients have Medicare as their primary insurance.	Spent $168,101.00 on Aranesp between March and August 2004.
Queens Nassau Nephrology Services 877 Stewart Ave, Suite 1 Garden City, NY	6 physicians, 10 ancillary staff	October 28, 2003	Primarily nephrology and significant portion of internal medicine patients.	40% of the patients have Medicare as their primary insurance.	In September 2003, the practice spent $5,107.20 on Aranesp.
South Texas Kidney Specialist 910 S. Bryan Road Suite 204 McAllen, Texas	4 physicians 1 Physician Assistant	November 18, 2003	Nephrology	80% of the patients have Medicare as their primary insurance.	Spent $222,289.00 on Aranesp between March and August 2004.
South Carolina Nephrology and Hypertension 1184 Orangeburg Mall Road Orangeburg, SC 29115	3 physicians	November 19, 2003	Nephrology	70% of the patients have Medicare as their primary insurance.	
Carabello Nephrology 201 S. Alvarado Street Ste. 410 Los Angeles, CA	3 physicians, 1 nurse	November 20, 2003	Nephrology	95% of the patients have Medicare as their primary insurance.	Spent $27,573.00 on Aranesp as at July 2004.
Clinical Nephrology Associates 205 North Broad Street Ste. 600 Philadelphia, PA	7 doctors, 2 nurses, 2 physician's assistant/nurse practitioners	November 7, 2003	Nephrology	60% of the patients have Medicare as their primary insurance.	In April 2004, this practice spent $19,843.60 on Aranesp.
Sakhrani and Minasian Nephrology Group 1427 S. Glendale Avenue Glendale, CA	5 physicians, 2.5 physician's assistants	December 15, 2003	Nephrology	40-60% of the patients have Medicare as their primary insurance.	Spent $61,709.40 on Aranesp between March and August 2004.

Practice	Details	Date of Assessment	Specialty	Medicare Population	Purchase
91205					
Milwaukee Nephrologists, SC St. Luke's Health Science Building 2901 W. Kinnickinnic River Prkwy Ste. 405 Milwaukee, WI 53215	11 physicians, 2 nurse practitioners (hospital based), 4 nurses (dialysis center based), 1.5 billing staff, 5.5 receptionist/sec, 1.0 Other Office Staff	December 11, 2003	Nephrology	80% of the patients have Medicare as their primary insurance.	Spent $11,060.28 on Aranesp in June 2004.
Nephrology, Hypertension and Transplant Nephrology 230 West Dares Beach Road, Ste. 106 Prince Fredrick, MD 20678	3 physicians	November 10, 2003	Nephrology	65% of the patients have Medicare as their primary insurance.	In July 2004, this practice spent $30,484.80 on Aranesp.
Renal Hypertension Physicians 1025 Briggs Road Ste 148 Mount Laurel. NJ 08054	7 physicians 1 nurse practitioner, 1 medical assistant	November 10, 2003	Nephrology	50% of the patients have Medicare as their primary insurance.	In October 2004, this practice spent $16,807.20 on Aranesp.
Vita Medical Center 6333 Wilshire Blvd Ste 200 Los Angeles, CA 90048	1 physician	November 20, 2003	Nephrology	95% of the patients have Medicare as their primary insurance.	

TABLE III
SAMPLE PURCHASES BY INN MEMBERS, COMPILED FROM INN TRACKING REPORTS

Providers in States that Were Plaintiffs:

Practice	Sample Purchase
CALIFORNIA	
California Kidney Medical Group, Simi Valley, CA	Spent $759,840.00 on Aranesp between March and August 2004.
Tower Nephrology, Los Angeles, CA	Spent $ 327,661.20 on Aranesp between March and August 2004.
Napa Valley Nephrology, Napa Valley, CA	Spent $ 118,316.40 on Aranesp between March and August 2004.
DELAWARE	
Nephrology Associates, Wilmington, DE	Spent $25,376.40 on Aranesp between September 1, 2003 and August 31, 2004
Nephrology Associates, Newark, DE	Spent $33,755.40 on Aranesp between September 1, 2003 and August 31, 2004
FLORIDA	
Boca Nephrology, Boca Raton, FL	Spent $1,327,596.00 on Aranesp between March and August 2004.
Main Street Medical, Dunedin, FL	Spent $428,128.80 on Aranesp between March and August 2004.
Gulf Coast Kidney Associates, Sarasota, FL	Spent $ 340,776.00 on Aranesp between March and August 2004.
GEORGIA	
Metro Atlanta Kidney Specialists, P.C., Atlanta, GA	Spent $214,560.60 on Aranesp between March and August 2004.
Renal Physicians of Georgia, P.C., Macon, GA	Spent $144,517.80 on Aranesp between March and August 2004.
North Georgia Nephrology Consultants, Athens, GA	Spent $41,256.00 on Aranesp between March and August 2004.
HAWAII	
Waimea Medical Associates, Kamuela, HI	Spent $18,753.00 on Aranesp between September 1, 2003 and August 31, 2004
ILLINOIS	
J.R. Nephrology, Oaklawn, IL	Spent $10,342.08 on Aranesp in May 2004.
Kidney Specialists of Central Illinois, Decatur, IL	Spent $419,316.00 on Aranesp between March and August 2004.
Central Illinois Kidney and Dialysis Associates, Springfield, IL	Spent $184,423.20 on Aranesp between March and August 2004.
INDIANA	
Southern Indiana Nephrology and Hypertension Center, Columbus, IN	Spent $27,291.60 on Aranesp in May 2004.

LOUISIANA	
Northwest Louisiana Nephrology, Shreveport, LA	Spent $10,198.44 on Aranesp in May 2004.
MASSACHUSETTS	
Jeffrey D. Horowitz and Thomas A. Krahn, Fall River, MA	Spent $ 32,462.64 on Aranesp in May 2004.
MICHIGAN	
Nephrology Associates of Michigan Ypsilanti, MI	Spent $28,009.80 on Aranesp in April 2004.
NEVADA	
Nephrology and Endocrine Associates, Las Vegas, NV	Spent $50,194.20 on Aranesp between September 1, 2003 and August 31, 2004.
NEW MEXICO	
University of New Mexico Sciences Center	Spent $142,880.00 on Aranesp in 2005.
CKD Services, Santa Fe, NM	Spent $998.00 on Aranesp.
Lovelace Clinic, Albuquerque, NM	Spent $36.00 on Aranesp.
NEW YORK	
Albert M. Defabritus M.D., New York, NY	Spent $2,585.52 on Aranesp in May 2004.
TENNESSEE	
Cumberland Kidney Center, Crossville, TN	Spent $861.84 on Aranesp in May 2004.
TEXAS	
Milton A. Giron, M.D. of Amarillo, TX	Spent $3,591.00 on Aranesp in April 2004.
San Antonio Nephrology Associates, San Antonio, TX	Spent $4,309.20 on Aranesp in May 2004.
Permian Nephrology Associates, Midland, TX	Spent $7,182.00 on Aranesp in May 2004.
San Antonio Kidney Disease Center Physicians Group, San Antonio, TX	Spent $1,014,376.80 on Aranesp between March and August 2004.
Kidney and Blood Pressure Center, San Antonio, TX	Spent $849,903.00 on Aranesp between March and August 2004.
West Texas Nephrology Associates, San Angelo, TX	Spent $567,504.00 on Aranesp between March and August 2004.
VIRGINIA	
New River Nephrology, Christiansburg, VA	Spent $4,596.48 on Aranesp in May 2004.

Providers in non-Plaintiff States:

ALABAMA	
Athens Internal Medicine and Nephrology Associates, Athens, AL	Spent $14,794.92 on Aranesp in May 2004.
ARKANSAS	
South Nephrology and Hypertension Clinic, Pine Bluff, AR	Spent $9,192.96 on Aranesp in May 2004.
COLORADO	
Summit Medical Clinic, Colorado Springs, CO	Spent $2,298.24 on Aranesp in May 2004.
CONNECTICUT	
Metabolism Associates, New Haven, CT	Spent $21,147 on Aranesp between September 1, 2003 and August 31, 2004.
IDAHO	
Idaho Nephrology Associates, Boise, ID	Spent $17,875.20 on Aranesp between September 1, 2003 and August 31, 2004.
IOWA	
Renal Associates, Sioux City, IA	Spent $31,743.60 on Aranesp between March and August 2004.
KANSAS	
Kansas Medical Clinic, P.A., Topeka, KS	Spent $33,330.60 on Aranesp between March and August 2004.
KENTUCKY	
Tri State Nephrology Associates, Ashland, KY	Spent $4,309.20 on Aranesp in May 2004.
MARYLAND	
Metropolitan Nephrology Associates, Clinton, MD	Spent $4,883.76 on Aranesp in May 2004.
MINNESOTA	
Dakota Clinic, Thief River Falls, MN	Spent $104,139 on Aranesp between September 1, 2003 and August 31, 2004.
MISSISSIPPI	
Nephrology and Hypertension Ltd., Tupelo, MS	Spent $23,987.88 on Aranesp in May 2004.
MISSOURI	
Branson Nephrology, Branson, MO	Spent $6,032.88 on Aranesp in May 2004.
NEBRASKA	
Wagoner Medical Group, Grand Island, NE	Spent $6,543.60 on Aranesp between September 1, 2003 and August 31, 2004.
NEW JERSEY	
Renal Hypertension Physicians, P.A., Mount Laurel, NJ	Spent $9,480.24 on Aranesp in May 2004.
NORTH CAROLINA	

Carolina Kidney Associates P.A., Greensboro, NC	Spent $2,298.24 on Aranesp in May 2004.
NORTH DAKOTA	
Great Plains Clinic, Dickinson, ND	Spent $11,491.20 on Aranesp between September 1, 2003 and August 31, 2004.
OHIO	
George Varghese, M.D. and Associates Inc., Springfield, OH	Spent $21,911.40 on Aranesp between March and August 2004.
OKLAHOMA	
Anupa Khastigir, M.D., Oklahoma City, OK	Spent $20,289.60 on Aranesp between March and August 2004.
OREGON	
Kidney and Hypertension Center P.C., Roseberg, OR	Spent $15,513.12 on Aranesp in May 2004.
PENNSYLVANIA	
Nephrology Hypertension Associates of Lehigh Valley, Easton, PA	Spent $8,618.40 on Aranesp in May 2004.
RHODE ISLAND	
Nephrology Associates, East Providence, RI	Spent $ 7,341.60 on Aranesp between September 1, 2003 and August 31, 2004
UTAH	
Southern Utah Neurology Center, Ivins, UT	Spent $30,324 on Aranesp between September 1, 2003 and August 31, 2004.
WASHINGTON	
East Side Nephrology and Hypertension, Bellevue, WA	Spent $38, 880 on Aranesp between March and August 2004.
WEST VIRGINIA	
Westvaco Family Medical Center, Piedmont, WV	Spent $2,872.80 on Aranesp between September 1, 2003 and August 31, 2004.
Hospital Plaza, Clarksburg, WV	Spent $159,679.80 on Aranesp between September 1, 2003 and August 31, 2004
WISCONSIN	
Milwaukee Nephrology CKD Clinic, Milwaukee, WI	Spent $16,662.24 on Aranesp in May 2004.
WYOMING	
Associates in Internal Medicine, Cheyenne, WY	Spent $23,616.00 on Aranesp between March and August 2004.

TABLE IV
EXAMPLES OF MEDICARE CLAIMS BILLED TO AND PAID BY MEDICARE

Rockland Renal Associates
Centerock East - 2 Crosfield Ave, Suite 312
West Nyack, NY 10994

Medicare Part B Billing (count=number of claims)

	year of service Data													
	2001		2003		2004		2005		2006		2007		2008	
ProvUPIN	Count	Sum of Pmt	Count	Sum of Pmt	Count	Sum of Pmt	Count	Sum of Pmt	Count	Sum of Pmt	Count	Sum of Pmt	Count	Sum of Pmt
[redacted]					218	$208,636	264	$260,740	171	$105,179	228	$186,817	60	$42,293
	1	$0			539	$528,370	751	$807,284	565	$330,076	679	$532,588	157	$110,325
	1	$0	4	$3,034	410	$342,578	568	$495,225	482	$254,553	693	$447,088	170	$97,320

Part A Billing

	year of Data					
	2006		2007		2008	
UPIN	Count	Sum of Pmt	Count	Sum of Pmt	Count	Sum of Pmt
JONATHAN S WOLF [redacted]	177	$471,583	231	$699,640	93	$234,847
STEVEN B YABLON	95	$225,889	124	$293,315	51	$107,631
KENNETH S SHAPIRO	992	$2,355,107	1,452	$3,576,475	484	$1,177,431

TABLE V

The following clinics were purchasing another ESA rather than Aranesp at the time they enrolled with INN. However, after their enrollment, they stopped purchasing any other ESA and instead bought Aranesp to the exclusion of any other ESA:

NAME	LOCATION	ENROLLED
Northwest Louisana Nephrology	Shreveport, LA	March 04
Mid-Atlantic Nephrology Associates		Jan 04
Renal Specialists of Naples	Naples, FL	Feb 04
Milwaukee Nephrology Ckd	Glendale, WI	Oct 03
Naushad Zafar, M.D.	San Antonio, TX	March 04
Bashar Alzahabi, M.D.	Effingham, IL	Feb 04
Associates in Internal Medicine and Nephrology	Norfolk, VA	Jan 04
Coastal Nephrology Associates	Punta Gorda, FL	May 04
Renal Associates	Sioux City, IA	April 04

DEFENDANT AMGEN'S UNLAWFUL RETALIATION AGAINST RELATOR

389. In or about March 2004, Relator left the Aranesp sales force and accepted a promotion to become an Aranesp Product Manager, which required Relator to relocate from Portland, Oregon to Amgen's home office in Thousand Oaks, California. As part of Relator's new position in Amgen's marketing department, Relator was assigned responsibility for Amgen's relationship with Defendant INN (a Group Purchasing Organization), which Relator had been told was an independent entity that focused on nephrology practices and physicians.

390. After Relator relocated to California and began working in Amgen's marketing department, Relator became privy to certain information and documentation that caused Relator to begin to question various aspects of the Amgen and INN relationship, and whether INN was, in fact, an independent GPO, or rather, an entity that essentially functioned as a *de facto* marketing arm for Amgen and for Aranesp. Relator learned, for example, that INN routinely

shared highly confidential information with Amgen concerning INN's business operations, including detailed information regarding certain nephrologists and nephrology practices that INN did business with, the revenues and finances of INN customers, and how many "untreated" chronic kidney disease patients any particular nephrology office had. In turn, Amgen provided INN with "target lists" that included the names and addresses of its nephrology customers that purchased Aranesp and/or purchased competing drugs. Defendants Amgen and INN traded this information back and forth for the purpose of helping either or both generate more business, reap higher profits, and/or convert non-Aranesp doctors and nephrology practices to Aranesp.

391. At or about the same time, Relator learned that wholesaler Defendant ASD Healthcare (which is owned by ABC and ABSG) was knowingly working with Amgen sales representatives and INN to obtain customers, and vice versa. For example, ASD representatives would "buddy up" with Amgen sales representatives and tell the Amgen representatives that they would give a big customer a better price on Aranesp. The Amgen representatives would create an economic spreadsheet concerning the proposed transaction to demonstrate to the customer the higher profit it would realize if it purchased its Aranesp through ASD Healthcare.

392. This "marketing" technique was employed both with respect to purchasers who already were using Aranesp but buying it from another wholesaler (not ASD Healthcare), and with respect to prospective customers who were using Procrit, which the Amgen sales representative (and INN) were trying convert to Aranesp.

393. Relator learned that ASD Healthcare would even offer prospective customers discounts on Procrit to lure that customer to become affiliated with ASD Healthcare, with the main objective being to convert the account to Aranesp once the customer had switched to ASD Healthcare.

394. ASD Healthcare, Amgen and INN were working together to target customers from different sales perspectives, while the prospective customer had no idea that the different representatives were talking to each other and sharing information, and that each company was attempting to direct the other's business.

395. Relator learned that Amgen was funneling large amounts of money to INN ostensibly identified as "administrative fees," when in fact the money was being used to arrange and subsidize all expenses paid "retreats" or "educational seminars" for targeted physicians and/or large nephrological practice groups (the names of which Amgen provided to INN), and/or to provide extra discounts to customers and/or high dollar volume "target accounts." In addition to high dollar accounts, certain of these "target accounts" had important political ties to influential nephrology associations throughout the country and had the ability to influence governmental reimbursement rates for Amgen drugs.

396. INN promoted and marketed these retreats/seminars and conducted the programs as if they were INN sponsored events, when in fact, all of the funding came from Amgen.

397. Moreover, INN and Amgen representatives would lead "informational" sessions at the retreats that placed heavy emphasis on Aranesp, to the exclusion of any competing drugs, and which placed heavy emphasis on the economic benefit that the physicians would realize if they purchased and administered Aranesp instead of competing drugs.

398. By Amgen directing business to INN, and INN targeting and converting these accounts, it potentially cost the government millions of dollars because the majority of these patients are Medicare/Medicaid patients, and because Aranesp had a higher reimbursement rate than competing drugs.

399. In conjunction with Amgen, INN sold this price "spread' to physicians, along with help from Amgen sales representatives. INN and Amgen representatives also encouraged the billing for overfill, as well as the conversion of Epogen dialysis business to Aranesp, which also made the physicians significantly larger profits since an Aranesp dialysis reimbursement rate had not yet been established.

400. Relator learned that INN representatives intentionally concealed INN's direct relationship with Amgen from its customers, and conveyed the impression that INN was an independent organization with no affiliation or ties to Amgen. In fact, INN was not independent of Amgen, as it essentially functioned as a marketing arm of Amgen, engaging in marketing practices on Amgen's behalf that Amgen fully supported and condoned.

401. For example, INN representatives would go into doctors' offices and meet with doctors, billing managers, office managers, etc., ostensibly to help them find billing errors or ways to increase reimbursement and revenue, or to offer or promote ancillary services that would improve office efficiency and economics.

402. INN also prepared Physician Assessment Forms and then, unbeknownst to the physician, shared the results with Amgen, and Defendants would formulate a plan to get the doctor to switch to Aranesp.

403. In addition, Amgen employees and INN representatives together would conduct "chart audits" of patient records/charts in doctor's offices and clinics.

404. As Relator became aware of the above information, Relator became more and more concerned about the relationship between INN and Amgen, and about the specific activities that she had become aware of.

405. In Fall 2004, Relator approached her immediate supervisor, Laurence "Matt" Skelton, and told Mr. Skelton that she was concerned about the propriety and legality of the INN/Amgen relationship, was concerned about the way INN was being used by Amgen to market Aranesp, and was concerned that she was unclear and uncertain as to what activities were authorized and legal and what activities were unauthorized and illegal.

406. At about the same time, Relator communicated these same concerns to another of her supervisors, Ray Chow.

407. Relator had multiple discussions with both Mr. Skelton and Mr. Chow in the second half of 2004 and early 2005 about her concerns regarding the propriety and/or legality of the relationship between INN and Amgen generally, and the above-described sales and marketing activities specifically.

408. In early 2005, after Relator had become more vocal about her concerns regarding the INN/Amgen relationship – specifically stating that she believed the INN/Amgen relationship to be improper and/or illegal in many respects – Relator was relieved of her INN responsibilities and was told that she no longer would be involved in, or have any responsibility for, the INN/Amgen relationship.

409. When Relator thereafter continued to express concerns about aspects of the INN/Amgen relationship – such as the lavish all-expenses-paid weekend retreats that were being contemplated and/or scheduled – Relator was told by Mr. Skelton and/or Mr. Chow to "stay out of it," that it "wasn't Relator's problem anymore because INN was now being handled by someone else."

410. The more Relator continued to express her concerns regarding INN, the more Messrs. Skelton and Chow became nervous and uncomfortable being around Relator. Indeed,

Mr. Skelton told Relator that he was relieved when Relator's INN responsibilities had been taken away because Relator now "could not complain to him anymore about it being wrong."

411. In early 2005, at approximately the same time that Relator's INN responsibilities were taken away, and about the same time that Relator was told by Messrs. Skelton and Chow to "stay out of [INN]," Amgen questioned certain of Relator's previously submitted and approved expense reports, and falsely accused Relator of having misused her expense account and of submitting false expense reports.

412. Messrs. Skelton and Chow made these accusations despite the fact that Relator had prepared and electronically submitted monthly expense reports pursuant to Amgen's policies and procedures, which had been subject to prior contemporaneous audit by Amgen representatives.

413. Nevertheless, Messrs. Skelton and Chow advised Relator that she would be required to undergo an audit of past expense items that previously had been submitted and approved, to be conducted outside the ordinary procedures by Messrs. Skelton and Chow.

414. Despite the fact that Relator had followed company policy and directives regarding her expense account, Messrs. Skelton and Chow advised Relator that she would be expected to reimburse Amgen for certain items that were deemed inappropriate business expenses.

415. Relator complained to Messrs. Skelton and Chow that she was being singled out in that fashion, and that Relator's expense accounting procedures were no different from any of the other Sales and Marketing team.

416. Relator was particularly concerned about her expense audit, because Mr. Skelton previously had told Relator that a "favorite method" of retaliating against employees or forcing

employees to quit was to commence aggressive audits relating to that employee's expense reports.

417. When Relator told Messrs. Skelton and Chow that she expected any expense audit to be conducted by the appropriate finance department supervisors, she was subjected to verbal threats and abuse by Messrs. Skelton and Chow.

418. Relator thereafter was told by Mr. Skelton that she would be required to reimburse Amgen for many thousands of dollars of expenses that previously had been approved, and that if Relator did not immediately write a check to Amgen in the requested amount, that Relator's employment with Amgen would be terminated.

419. Messrs. Skelton and Chow also told Relator that, in order to continue her employment with Amgen, she also would be required to sign a document "acknowledging" the issues with her expense reports, although they purported to promise to Relator that they would not show the document to anyone else (not even Amgen's Human Resources department) or use it in any manner. Messrs. Skelton and Chow told Relator that the document was "just for their files."

420. The stress and anxiety resulting from the series of confrontations with her superiors as set forth above caused Relator to go on temporary disability leave from Amgen in March 2005. Relator remained on disability for an extended period of time until she eventually was terminated.

421. Amgen was aware that Relator's expense reports were consistent with company practices, yet nonetheless her supervisors harassed her about them, in an attempt to retaliate against her for raising issues regarding Defendants' relationships and misconduct.

422. In fact, regardless what Amgen's corporate compliance manuals stated for public consumption, Amgen encouraged its sales representatives to incur lavish expenses to entertain medical professionals and to minimize the documentation provided about such expenses.

423. That issue was so prevalent and obvious at Amgen during the time of Relator's employment and thereafter, that the script for the July 2007 meeting of Amgen's Nephrology Business Unit from the files of Amgen Vice President of Sales Leslie Mirani included not only a joke about black box warnings, but also a joke about the fact that "expense reports without receipts" and "taking a wine-loving doc[tor] to dinner" were under "reimbursement pressure" along with reimbursement for ESAs, such as Aranesp.

424. As set forth in detail above, Amgen threatened, harassed, intimidated and otherwise discriminated against Relator directly because of her lawful acts involving a potential violation(s) of the False Claims Act by Amgen regarding its unlawful relationship and activities with Defendant INN. By these actions, Amgen violated the False Claims Act, 31 U.S.C., § 3730(h), as set forth below.

425. Relator has been damaged as a direct result of these illegal actions, and has suffered great economic harm, loss of income, and emotional injury.

CLAIMS ON BEHALF OF THE UNITED STATES OF AMERICA

COUNT ONE
FALSE CLAIMS ACT

ALL DEFENDANTS

Defendants Knowingly Caused the Submission of False and/or Fraudulent Claims by Providers in Violation of 31 U.S.C. § 3729 (a)(1)(A) Because Such Claims were not for Aranesp that was Medically Indicated for the Health of the Patient and/or was not Administered in the Number of Units Claimed

426. The named Plaintiff the United States of America has filed a notice of not intervening at this time. On behalf of the United States, Relator restates and realleges the allegations in paragraphs 1 through 425 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

427. This is a claim for treble damages and monetary penalties pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, as amended.

428. Through the acts and omissions described herein, and from at least on or before September 2001 to the present, Defendants knowingly caused medical providers throughout the United States to present for payment and approval false and/or fraudulent claims to officers of the United States Government, including without limitation, claims submitted to Medicare on CMS Form 1500 claims forms and other claims submitted for payment from federal funds.

429. Defendants induced providers through kickbacks described in this Complaint and other statements and representations to present claims to Medicare for reimbursement based on alleged provision of medical services that were unnecessary and/or not actually rendered. Defendants' kickbacks and other misconduct tainted the medical providers' services and the resulting claims are materially false and/or fraudulent. *See United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 2010 WL 938361, at *16 (D. Mass March 12, 2010).

430. As described herein, such claims were false and/or fraudulent because:

(a) by signing the form (see, e.g., Box 31), the provider certified that the Aranesp units administered were "medically indicated and necessary for the health of the patient" (see reverse side of claim form), when in fact, they were not; and

(b) by signing the form (*see, e.g.*, Box 31), the provider certified that the number of units shown on the form as being administered (see, e.g., Box 24G) were actually administered or furnished (see also reverse side of claim form) when, in fact, they were not.

431. Moreover, such claims were submitted for payment in violation of provisions of the Medicare statute and regulations, which specify that services are only covered or reimbursable when "medically indicated and necessary." *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(A) ("nonpayment may be made [under the Medicare statute] for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury"). It is axiomatic that claims submitted for goods or services that were not actually provided to patients are factually false claims and are not reimbursable by Medicare.

432. In addition to the other specific certifications and statements cited in this Complaint, the reverse side of the claim form, which is expressly incorporated into the provider's signature in Box 31, contains three explicit notices to the provider:

> NOTICE: Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties.
>
> NOTICE: Anyone who misrepresents or falsifies essential information to receive payment from Federal funds requested by

> this form may upon conviction be subject to fine and imprisonment under applicable Federal laws.
>
> NOTICE: this is to certify that the foregoing information is true, accurate and complete. I understand that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws

Exhibit K.

433. The Medicare Provider Enrollment Application contains similar representations and certifications and warnings, as does the two-page PECOS certification form.

434. The claim forms were false and/or fraudulent because the claims falsely represented on their face that the provider had administered Aranesp in a dose that was "medically indicated and necessary and indicated for the health of the patient" when, in fact, the patient had been administered more than the labeled fill volume on the Aranesp vial, *i.e.*, had been administered units of Aranesp that were not intended to be administered to patients.

435. Moreover, in many instances, providers administered Aranesp overfill units across the board, to every patient in the practice or a group of patients, because of standing orders or other protocols that were not based on assessment of what was "medically indicated and necessary" for each patient's health.

436. Such overdosing of patients was not medically indicated and necessary; indeed, it was contraindicated particularly in light of the serious adverse safety risks to patients from overdosing of Aranesp (and other ESAs).

437. The related claims were submitted for payment in violation of the Medicare statute and regulations which specify that services are only covered or reimbursable when "medically indicated and necessary." "Since § 1395y(a)(1)(A) expressly prohibits payment if a

provider fails to comply with its terms, defendants' submission of the claim forms implicitly certifies compliance with its provision." *Mikes*, 274 F.3d at 701. Moreover, the Provider Enrollment Application makes clear that continued compliance with the Anti-Kickback Statute is a condition of payment for any claim.

438. The claim forms were also false and/or fraudulent because, as Amgen's own analyses and other evidence demonstrates, it was not feasible for providers to be able to withdraw or capture and administer anywhere near the full amount of overfill from every Aranesp vial.

439. Nevertheless, based on Defendants' presentations and instructions on Medicare claims submission, providers would seek reimbursement from Medicare on CMS 1500 claim forms for all or a very large portion of the Aranesp overfill in every vial. As Defendants were aware, the providers, however could not (and did not) administer the Aranesp overfill as stated on the claims forms to any patient.

440. Defendants caused the claims for Aranesp described in this Count to be submitted for Medicare reimbursement when Defendants knew (within the meaning of the FCA) that such claims were not eligible for reimbursement in whole or in part, and it was a natural and foreseeable consequence of Defendants' misconduct that providers would submit such claims.

441. Providers submitted such claims as a natural and foreseeable result of the illegal marketing and promotional activity of Defendants described in this Complaint including without limitation, Defendants' making of oral and written statements to providers that showed or illustrated to them the amount of overfill contained in the Aranesp vial, compared the same to the overfill contained in Procrit vials, showed extra reimbursement and profit that could be made from billing the Aranesp single dose vial overfill (versus, e.g., the Procrit multi-dose vial

overfill) to Medicare, encouraged the use of standing orders or protocols despite the fact that Aranesp should be dosed according to each particular patient's medical condition, and advised providers how they could "pass an audit" by the Government.

442. Government Health Care Program officials, their contractors, carriers, intermediaries and agents, paid and approved claims for payment for Aranesp that should not have been paid or approved.

443. Defendants, through the means described above, deliberately and intentionally concealed material information, including the false or fraudulent nature of the claims, from officials with Government Health Care Programs, and other Government officials, their contractors, carriers, intermediaries and agents, in order to induce payment of the false or fraudulent claims.

444. Government Health Care Program officials and their contractors, carriers, intermediaries and agents, would not have paid the claims for Aranesp had they known the truth.

445. By reason of the above-described actions and the submission of claims that were false and/or fraudulent, the United States has suffered significant losses in an amount to be determined.

COUNT TWO
FALSE CLAIMS ACT

ALL DEFENDANTS

Defendants Knowingly Caused the Submission of False and/or Fraudulent Claims in Violation of 31 U.S.C. § 3729 (a)(1)(A) by Offering Overfill as Illegal Remuneration to Induce Providers to Purchase Aranesp in Violation of the Anti-Kickback Statute

446. The named Plaintiff the United States of America has filed a notice of not intervening at this time. On behalf of the United States, Relator restates and realleges the

allegations in paragraphs 1 through 445 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

447. This is a claim for treble damages and monetary penalties pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, as amended.

448. From at least 2001 to present, Amgen and INN knowingly offered kickbacks to medical providers in the form of overfill contained in vials of Aranesp and encouraged medical providers to submit claims for payment for the free product.

449. Through the acts and omissions described herein, and from at least on or before September 2001 to the present, Defendants knowingly caused medical providers to present for payment and approval false and/or fraudulent claims to officers of the United States Government, including without limitation, claims submitted to Medicare on CMS Form 1500 claims forms and other claims submitted for payment from federal funds.

450. As described herein, such claims were false and/or fraudulent because:

(a) by signing the form (*see, e.g.*, Box 31), the provider certified that the Aranesp units administered were "medically indicated and necessary for the health of the patient" (see reverse side of claim form), when in fact, they were not and were therefore not reimbursable by Medicare. *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(A) ("nonpayment may be made [under the Medicare statute] for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury"). "Since § 1395y(a)(1)(A) expressly prohibits payment if a provider fails to comply with its terms, defendants' submission of the claim forms implicitly certifies compliance with its provision." *Mikes*, 274 F.3d at 701; and

(b) The kickbacks by Defendants tainted the services and the resulting claims are false, and materially false, including that medical services provided based on, because of, or by reason of a kickback are *per se* not "reasonable and necessary for the diagnosis or treatment of illness or injury."

451. The submitted CMS 1500 claim forms also contain "misrepresentations" and "false, incomplete or misleading information," or "misrepresent essential information to receive payment," are not "true, accurate and complete," and are based upon "concealment of a material fact," including that the provider was offered and accepted a kickback which tainted the claim and rendered it ineligible for payment. Providers on are notice from Form 855 that each claim was "conditioned upon the claim and the underlying transaction complying with . . . the Federal anti-kickback statute." CMS 855. The claim forms are thereby rendered "false" and "fraudulent" within the meaning of the FCA.

452. The submitted CMS 1500 claims forms seek (and have resulted in) payment of government money to which the provider is not entitled and that the Government paid by mistake, which constitutes a violation of the FCA.

453. Violation of the Anti-Kickback Statute renders related claims, such as the submitted CMS 1500 claims forms *per se* false or fraudulent, including because:

(a) Compliance with the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, is a condition of payment under the Medicare program. *United States ex rel. Westmoreland v. Amgen Inc.*, No. 06-10972-WGY, 2010 WL 1634315, at *8 (D. Mass. Apr. 23, 2010);

(b) The legislative history of the 1986 amendments to the FCA also make clear that violation of the Anti-Kickback Statute renders claims false ("[A]

false claim may take many forms, the most common being a claim for goods or services not provided, *or provided in violation of contract terms, specification, statute or regulation* …" S. Rep. No. 345, 99th Cong., 2d Sess. 9 (1986), U.S.C.C.A.N. 5266, 5274 (emphasis added));

(c) The legislative history of the 2009 amendments to the FCA[6] make clear that violation of the Anti-Kickback Statute renders a claim false (*e.g.*, Cong. Rec. E1296-97 (Rep. Berman stating that among the various types of conduct that, when done knowingly, violate the Act, are "submitting a claim for payment even though the defendant was violating the Government-funded program's conditions of participation of payment; fraudulently cashing a Government check or knowingly keeping Government funds that were initially wrongfully or mistakenly obtained.")); and

(d) Congress has since eliminated any conceivable argument that the False Claims Act does not reach claims tainted by a violation of the Anti-Kickback Statute. On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119. In that Act (at p. 1703 of the Act, Section 10104(f)), Congress included an amendment to the Anti-Kickback Statute, stating that "a claim that includes items or services

6 Because Relator's case was pending as of June 7, 2008, "the potentially applicable provisions in this case are former § 3729(a)(1), establishing liability for 'knowingly present[ing], or cause[ing] to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval," and current § 3729(a)(1)(B), establishing liability for 'knowingly mak[ing], us[ing], or caus[ing[to be made or used, a false record or statement material to a false or fraudulent claim." *United States ex rel. Kirk v. Schindler Elevator Corp.*, --- F.3d ---, Docket No. 09-1678-cv, 2010 WL 1292143, at *14 (2d Cir. Apr. 6, 2010) (quoting FERA §4(a), 123 Stat. at 1621).

resulting from a violation of this section constitutes a false or fraudulent claims for purposes of [the False Claims Act]."

454. Violation of the Anti-Kickback Statute rendered the providers ineligible to receive Medicare reimbursement for the submitted claims, particularly where a provider had recertified compliance with the Anti-Kickback Statute after having received any kickback from Defendants or otherwise.

455. Defendants caused such claims to be submitted for reimbursement for Aranesp when the Defendant knew (within the meaning of the FCA) that because of their offering overfill as a kickback such items or units of Aranesp were not eligible for reimbursement in whole or in part, and it was a natural and foreseeable consequence of Defendants' misconduct that providers would submit such claims.

456. Providers submitted such claims as a natural and foreseeable result of the illegal marketing and promotional activity of Defendants described in this Complaint including without limitation, Defendants' making of oral and written statements to providers that showed or illustrated to them the amount of overfill contained in the Aranesp vial, compared the same to the overfill contained in Procrit vials, showed extra reimbursement and profit that could be made from billing the Aranesp single dose vial overfill (versus, *e.g.*, the Procrit multi-dose vial overfill) to Medicare, encouraged the use of standing orders or protocols despite the fact that Aranesp should be dosed according to each particular patient's medical condition, and advised providers how they could "pass an audit" by the Government.

457. The unlawful overfill marketing and promotional activities made by Defendants resulted in claims which failed to disclose the material violations of the Anti-Kickback Statute

and other laws. As a result of this illegal activity, these claims were improper in whole pursuant to 31 U.S.C. § 3729(a)(1)(A).

458. Defendants knowingly caused to be presented false or fraudulent claims for Aranesp resulting from the kickbacks and thereby causing Government Health Care Programs, including the Medicare and Medicaid Programs, to reimburse ineligible claims.

459. Government Health Care Program officials, their contractors, carriers, intermediaries and agents, paid and approved claims for payment for Aranesp that should not have been paid or approved.

460. Defendants, through the means described above, deliberately and intentionally concealed material information, including the false and fraudulent nature of the claims, from officials with Government Health Care Programs, and other Government officials, their contractors, carriers, intermediaries and agents, in order to induce payment of the false and fraudulent claims.

461. Government Health Care Program officials and their contractors, carriers, intermediaries and agents, would not have paid the claims for Aranesp had they known the truth.

462. By reason of the above-described actions and the presentment of false or fraudulent claims, the United States has suffered significant losses in an amount to be determined.

COUNT THREE
FALSE CLAIMS ACT

DEFENDANTS INN AND ASD HEALTHCARE

Defendants Knowingly Caused the Submission of False and/or Fraudulent Claims in Violation of 31 U.S.C. § 3729 (a)(1)(A) by Offering Other Kickbacks as Illegal Remuneration to Induce Providers to Purchase Aranesp in Violation of the Anti-Kickback Statute

463. The named Plaintiff, the United States of America, has filed a notice of not intervening at this time. On behalf of the United States, Relator restates and realleges the allegations in paragraphs 1 through 462 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

464. This is a claim for treble damages and monetary penalties pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, as amended.

465. Through the acts and omissions described herein, and from at least on or before September 2003 to the present, Defendants knowingly caused medical providers to present for payment and approval false and/or fraudulent claims to officers of the United States Government, including without limitation, claims submitted to Medicare on CMS Form 1500 claims forms.

466. As described herein, such claims were false and/or fraudulent because:

(a) by signing the form (see, e.g., Box 31), the provider certified that the Aranesp units administered were "medically indicated and necessary for the health of the patient" (see reverse side of claim form), when in fact, they were not and were therefore not reimbursable by Medicare. *See*, *e.g.*, 42 U.S.C. § 1395y(a)(1)(A) ("nonpayment may be made [under the Medicare statute] for any

expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury"). "Since § 1395y(a)(1)(A) expressly prohibits payment if a provider fails to comply with its terms, defendants' submission of the claim forms implicitly certifies compliance with its provision." *Mikes*, 274 F.3d at 701; and

(b) The kickbacks by Defendants tainted the services and the resulting claims are false, and materially false, including that medical services provided based on, because of, or by reason of a kickback are *per se* not "reasonable and necessary for the diagnosis or treatment of illness or injury."

467. The submitted CMS 1500 claim forms also contain "misrepresentations" and "false, incomplete or misleading information," or "misrepresent essential information to receive payment," are not "true, accurate and complete," and are based upon "concealment of a material fact," including that the provider was offered and accepted a kickback which tainted the claim and rendered it ineligible for payment. The claim forms are thereby rendered "false" and "fraudulent" within the meaning of the FCA.

468. The submitted CMS 1500 claims forms seek (and have resulted in) payment of government money to which the provider is not entitled and that the Government paid by mistake, which constitutes a violation of the FCA.

469. Violation of the Anti-Kickback Statute renders related claims, such as the submitted CMS 1500 claims forms *per se* false or fraudulent.

470. Violation of the Anti-Kickback Statute rendered the providers ineligible to receive Medicare reimbursement for the submitted claims, particularly where a provider had recertified

compliance with the Anti-Kickback Statute after having received any kickback from Defendants or otherwise.

471. Defendants caused such claims to be submitted for reimbursement for Aranesp when the Defendant knew (within the meaning of the FCA) that because of their offering kickbacks, including compensation, travel, and other valuable benefits, the Aranesp claims were not eligible for reimbursement in whole or in part, and it was a natural and foreseeable consequence of Defendants' misconduct that providers would submit such claims.

472. Providers submitted such claims as a natural and foreseeable result of the illegal marketing and promotional activity of Defendants described in this Complaint including without limitation, Defendants' provision of compensation, travel, and other benefits to providers.

473. The unlawful marketing and promotional activities made by Defendants resulted in claims which failed to disclose the material violations of the Anti-Kickback Statute and other laws. As a result of this illegal activity, these claims were improper in whole pursuant to 31 U.S.C. § 3729(a)(1)(A).

474. Defendants knowingly caused to be presented false or fraudulent claims for Aranesp resulting from the kickbacks and thereby causing Government Health Care Programs, including the Medicare and Medicaid Programs, to reimburse ineligible claims.

475. Government Health Care Program officials, their contractors, carriers, intermediaries and agents, paid and approved claims for payment for Aranesp that should not have been paid or approved.

476. Defendants, through the means described in this Complaint, deliberately and intentionally concealed material information, including the false and fraudulent nature of the claims, from officials with Government Health Care Programs, and other Government officials,

their contractors, carriers, intermediaries and agents, in order to induce payment of the false and fraudulent claims.

477. Government Health Care Program officials and their contractors, carriers, intermediaries and agents, would not have paid the claims for Aranesp had they known the truth.

478. By reason of the above-described actions and the presentment of false or fraudulent claims, the United States has suffered significant losses in an amount to be determined.

COUNT FOUR
FALSE CLAIMS ACT

DEFENDANT AMGEN

Defendant Amgen Knowingly Caused the Submission of False and/or Fraudulent Claims by Providers in Violation of 31 U.S.C. § 3729 (a)(1)(A) Because Such Claims Were Tainted by a False or Fraudulent ASP for Aranesp

479. The named Plaintiff, the United States of America, has filed a notice of not intervening at this time. On behalf of the United States, Relator restates and realleges the allegations in paragraphs 1 through 478 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

480. This is a claim for treble damages and monetary penalties pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, as amended.

481. From at least 2001 to present, Amgen and INN knowingly offered kickbacks to medical providers in the form of overfill contained in vials of Aranesp, and encouraged medical providers to submit claims for payment for the free product.

482. Through the acts and omissions described herein, and from at least on or before January 1, 2005 to the present, the Defendants knowingly caused medical providers to present

for payment and approval false and/or fraudulent claims to officers of the United States Government including without limitation, claims submitted to Medicare on CMS Form 1500 claims forms and other claims submitted for payment from federal funds.

483. As described herein, such claims were false and/or fraudulent because the reimbursement rate at which CMS paid such claims, *i.e.*, the Average Sales Price for the drug, was misrepresented to CMS by Amgen. Defendant Amgen failed to include in its ASP calculation reported to CMS the overfill units of Aranesp provided to and accessible by every customer.

484. Defendant Amgen caused such claims to be submitted for reimbursement for Aranesp when Defendant knew (within the meaning of the FCA) that it had falsely and fraudulently caused the ASP to be higher than it truly was, which made prescribing Aranesp more lucrative for the provider. It was a natural and foreseeable consequence of Defendant's misconduct that providers would submit such claims.

485. Government Health Care Program officials, their contractors, carriers, intermediaries and agents, paid and approved claims for payment for Aranesp that should not have been paid or approved.

486. Defendant Amgen, through the means described above, deliberately and intentionally concealed material information, including the false or fraudulent nature of the claims resulting from the false ASP, from officials with Government Health Care Programs, and other Government officials, their contractors, carriers, intermediaries and agents, in order to induce payment of the false or fraudulent claims.

487. Government Health Care Program officials and their contractors, carriers, intermediaries and agents, would not have paid the claims for Aranesp had they known the truth.

488. By reason of the above-described actions and the submission of claims that were false and/or fraudulent, the United States has suffered significant losses in an amount to be determined.

COUNT FIVE
FALSE CLAIMS ACT

ALL DEFENDANTS

Defendants Knowingly Caused Providers to Make or Use False Records or Statements Material to Payment or Approval of a Claim in Violation of 31 U.S.C. § 3729 (a)(1)(B)

489. The named Plaintiff, the United States of America, has filed a notice of not intervening at this time. On behalf of the United States, Relator restates and realleges the allegations in paragraphs 1 through 488 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

490. This is a claim for treble damages and monetary penalties pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, as amended.

491. Through the acts and omissions described herein, and from at least on or before September 2001 to the present, Defendants knowingly caused medical providers to make or use false records or statements material to payment or approval of a claim, including without limitation, claims submitted to Medicare on CMS Form 1500 claims forms.

492. As described herein, such false records or statements include without limitation, the statements and records alleged above (including in Counts One-Three):

(a) False statements on the CMS 1500 form as to medical necessity;

(b) False statements on the CMS 1500 form as to units administered/services furnished;

(c) False statements on the CMS 1500 form as to the truthfulness, accuracy and completeness of the form, the absence of any material omission or

the concealment of a material fact (including concealment of kickbacks which render the claim ineligible for payment); and

(d) False statements on the Provider Enrollment Agreements as to compliance and continuing compliance with the terms of that agreement. Such false statements include both certifications of compliance with the Anti-Kickback Act at a time when those providers were receiving kickbacks from Aranesp in the form of overfill, as well as providers' failure to notify the government upon accepting overfill from Aranesp subsequent to signing the Provider Enrollment Agreement.

493. Defendants knowingly caused such false records or statements to be made, and knew that such records or statements were material to getting claims for Aranesp paid or approved. Defendants knew (within the meaning of the FCA) that because of their conduct, such claims for Aranesp were not eligible for reimbursement in whole or in part. It was a natural and foreseeable consequence of Defendants' misconduct that providers would submit make or use such records or statements.

494. Providers made or used such records or statements as a natural and foreseeable result of the illegal marketing and promotional activity of Defendants described in this Complaint including without limitation, the manner in which Defendants marketed Aranesp based on overfill and the provision of other kickbacks.

495. Government Health Care Program officials, their contractors, carriers, intermediaries and agents, paid and approved claims for payment for Aranesp that should not have been paid or approved.

496. Defendants deliberately and intentionally concealed the false and fraudulent nature of the claims from officials with Government Health Care Programs, and other Government officials, their contractors, carriers, intermediaries and agents, in order to induce payment of the false and fraudulent claims.

497. Government Health Care Program officials and their contractors, carriers, intermediaries and agents, would not have paid the claims for Aranesp had they known the truth.

498. By reason of the above-described actions and the presentment of false or fraudulent claims, the United States has suffered significant losses in an amount to be determined.

COUNT SIX
FALSE CLAIMS ACT

ALL DEFENDANTS

Defendants Conspired to Violate the False Claims Act by Getting False or Fraudulent Claims Allowed or Paid by the United States in Violation of 31 U.S.C. § 3729 (a)(1)(C)

499. The named Plaintiff, the United States of America, has filed a notice of not intervening at this time. On behalf of the United States, Relator restates and realleges the allegations in paragraphs 1 through 498 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

500. This is a claim for treble damages and monetary penalties pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, as amended.

501. Through the acts and omissions described in this Complaint, and from on or before at least 2003 to the present, Defendants, with each other and with persons known and unknown, knowingly agreed and conspired to defraud the federal and state governments by having false or fraudulent statements, records, certifications, and claims for Aranesp submitted to, paid and approved by Government Health Care Program officials, their contractors, carriers, intermediaries and agents.

502. From on or before 2003 to present, Defendants Amgen, INN, ASD Healthcare (and others) conspired to defraud the United States by knowingly offering kickbacks to medical

providers including in the form of overfill contained in vials of Aranesp and by understating the true ASP of Aranesp. In addition, INN and ASD Healthcare offered sham consultancy agreements, weekend retreats, price concessions/discounts, and/or other services, encouraging medical providers to present, make and/or use claims for payment that were ineligible for reimbursement, and understating the true ASP of Aranesp.

503. From at least 2003 to present, Defendants conspired to defraud the United States by knowingly causing medical providers to submit false certifications to Government Health Care Programs, including the Medicare and Medicaid Programs, that the provider was in compliance with state and federal laws, including the Anti-Kickback Statute.

504. From at least 2003 to present, Defendants conspired to defraud the United States by knowingly causing medical providers to present, make and/or use claims for Aranesp, thereby causing Government Health Care Programs, including the Medicare and Medicaid Programs, to reimburse ineligible claims.

505. By virtue of their conspiratorial agreement, Defendants caused to be presented, made and/or used false or fraudulent claims, and/or false records or statements, including provider certifications, to Government Health Care Programs, including the Medicare and Medicaid Programs, causing the United States to suffer significant damages.

506. The United States is therefore entitled to recover from Defendants treble damages under the federal FCA, in an amount to be proved at trial, plus a civil penalty of at least $5,500 for each violation.

COUNT SEVEN
FALSE CLAIMS ACT

ALL DEFENDANTS

Defendants Made and Caused to be Made Statements Material to a False or Fraudulent Record as Part of a Fraudulent Scheme

507. The named Plaintiff, the United States of America, has filed a notice of not intervening at this time. On behalf of the United States, Relator restates and realleges the allegations in paragraphs 1 through 506 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

508. This is a claim for treble damages and monetary penalties pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, as amended.

509. Through the acts and omissions described in this Complaint, and from on or before at least 2003 to the present, Defendants, with each other and with persons known and unknown, engaged in a overarching fraudulent scheme to systematically reap greater profits by boosting Aranesp sales using manufacturing and sales techniques that were fraudulent. Defendants, as part of this fraudulent scheme, knew that every claim submitted to a Government Health Care Program, would be tainted by Defendants' fraud, and would hence constitute a fraudulent claim under the FCA, thereby causing damages to Government Health Care Programs.

510. Defendants also knew that their statements and records made to medical providers would made and used in connection with a false or fraudulent claim by a medical provider.

CLAIMS ON BEHALF OF THE RELATOR PERSONALLY

COUNT EIGHT
FALSE CLAIMS ACT

AGAINST DEFENDANT AMGEN
Defendant Amgen's Unlawful Retaliation Against Relator Under 31 U.S.C. § 3730(h)

511. Relator restates and realleges the allegations in paragraphs 1 through 510 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

512. As set forth in detail above, Amgen threatened, harassed and otherwise discriminated against Plaintiff/Relator Westmoreland because of her lawful acts involving a potential violation(s) of the False Claims Act by her employer, Amgen. By these actions, Amgen violated the False Claims Act, 31 U.S.C. § 3730(h).

513. Plaintiff/Relator has been damaged as a direct result of these illegal actions. She has suffered great economic harm, loss of income and future earnings, and emotional injury.

514. Amgen's conduct as alleged herein was done knowingly, maliciously, oppressively, and with conscious disregard for the rights of Relator. Therefore, Relator is entitled to recover exemplary and punitive damages against Amgen in an amount to be determined at trial.

COUNT NINE
CALIFORNIA LAW

AGAINST DEFENDANT AMGEN
Defendant Amgen's Wrongful Termination of Relator and Violation of Public Policy Under California Law

515. By this reference, Relator hereby incorporates paragraphs 1 through 514 above, inclusive, as though set forth fully herein.

516. Amgen constructively terminated Relator's employment in March 2005, when Relator was forced to go on disability leave because of the harassment and retaliation that she suffered, as alleged above.

517. Amgen's termination of Relator was wrongful and in violation of public policy under California law because Relator was terminated based on her having voiced her legitimate and serious concerns to Amgen management about various unlawful practices of Amgen as concerned Amgen's relationship and activities with INN, and Amgen's illegal kickbacks, as alleged above.

518. Amgen's wrongful termination of Relator was done in violation of numerous laws and public policies, including (1) those that prohibit employer retaliation against employees who refuse to participate in unlawful activities (*e.g.*, Cal. Labor Code § 1102.5(c)); (2) those that protect an employee from retaliation by an employer based on the employee's having complained to management about unlawful activities (*see, e.g.*, *Green v. Ralee Eng. Co.*, 19 Cal. 4th 66, 85, 78 Cal. Rptr. 2d 16, 27 (1998); *Collier v. Superior Court*, 228 Cal. App. 3d 1117, 1123, 279 Cal. Rptr. 453, 455 (1991)); and (3) those that require a licensed pharmacist (like Relator) to adhere to various professional and ethical standards and precepts.

519. As a direct and proximate result of Amgen's wrongful conduct as alleged herein, Relator has suffered harm, including, but not limited to, lost past and future earnings, lost employment benefits (*e.g.*, health insurance benefits, and retirement contributions, job-search expenses, humiliation, embarrassment, mental anguish, and severe emotional distress – all to her damage in an amount to be determined at trial.

520. Amgen's conduct as alleged herein was done knowingly, maliciously, oppressively, and with conscious disregard for the rights of Relator. Therefore, Relator is

entitled pursuant to § 3294 of the California Civil Code to recover exemplary and punitive damages against Amgen in an amount to be determined at trial.

PRAYERS FOR RELIEF

WHEREFORE, Relator, acting on behalf of and in the name of the United States of America, and on her own behalf, demands and prays that judgment be entered as follows:

(a) In favor of the United States against the Defendants jointly and severally for treble the amount of damages to Government Health Care Programs from the illegal marketing, selling, prescribing, pricing and billing alleged herein, plus maximum civil penalties of Eleven Thousand Dollars ($11,000.00) for each false claim;

(b) In favor of the United States against the Defendants for disgorgement of the profits earned by Defendants as a result of their illegal schemes;

(c) In favor of the Relator for the maximum amount allowed as a Relator's share pursuant to 31 U.S.C. § 3730(d) and in favor of Relator against Defendants for reasonable expenses, attorneys' fees and costs incurred by Relator;

(d) In favor of the Relator and the United States and against the Defendants for all costs of this action;

(e) In favor of the Relator and the United States and against the Defendants for such other and further relief as this Court deems to be just and equitable;

(f) In favor of the Relator for the maximum amount allowed as a Relator's share pursuant to the State FCAs as follows: Cal. Gov't Code 12652(g); Del. Code Ann. Tit. 6, § 1205; D.C. Code § 2-308.14(f); Fla. Stat. § 68.085; Official Code of Georgia Annotated, 49-4-168; Haw. Rev. Stat. § 661-27; 740 Ill. Comp. Stat.

§ 175/4(d); IC 5-11-5.5; 46 La. Rev. Stat. c. 3, § 437.1 et seq.; Mass. Gen. Laws Ch. 12, § 5F; Nev. Rev. Stat. §§ 357.210, 357.220, MI ST Ch. 400; N.H. RSA §§ 167:61-b; N.M. Legis 49 (2004); Chapter 4, NY laws 58, s. 39, Art. XIII, §189; Tenn. Code Ann. § 71-5-183(c); Tex. Hum. Res. Code § 36.110, and Va. Code Ann. § 8.01-216.7;

(g) In favor of the Relator and against the Defendants for all costs and expenses associated with the supplemental State claims, including attorneys' fees and costs;

(h) In favor of the State Plaintiffs and the Relator and against the Defendants for all such other relief as the Court deems just and proper; and

(i) In favor of Relator Westmoreland against Defendant Amgen for all available damages and relief under 31 U.S.C. § 3730(h), and California law, including, without limitation, two times back pay plus interest (and prejudgment interest), reinstatement or in lieu thereof front pay, and compensation for any special damages and/or exemplary or punitive damages, and litigation costs, and attorneys' fees.

PLAINTIFF/RELATOR DEMANDS A TRIAL BY JURY ON ALL COUNTS

May 27, 2010

Respectfully submitted,

RELATOR KASSIE WESTMORELAND

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on May 28, 2010.

/s/ Silvija A. Strikis

EXHIBIT A

ARANESP NDCS

NDC_CODE	FORM_DESC
55513000201	ARANESP 25 MCG/ML VIAL
55513000204	ARANESP 25 MCG/ML VIAL
55513000301	ARANESP 40 MCG/ML VIAL
55513000304	ARANESP 40 MCG/ML VIAL
55513000401	ARANESP 60 MCG/ML VIAL
55513000404	ARANESP 60 MCG/ML VIAL
55513000501	ARANESP 100 MCG/ML VIAL
55513000504	ARANESP 100 MCG/ML VIAL
55513000601	ARANESP 200 MCG/ML VIAL
55513001001	ARANESP 25 MCG/ML VIAL
55513001004	ARANESP 25 MCG/ML VIAL
55513001101	ARANESP 40 MCG/ML VIAL
55513001104	ARANESP 40 MCG/ML VIAL
55513001201	ARANESP 60 MCG/ML VIAL
55513001204	ARANESP 60 MCG/ML VIAL
55513001301	ARANESP 100 MCG/ML VIAL
55513001304	ARANESP 100 MCG/ML VIAL
55513001401	ARANESP 200 MCG/ML VIAL
55513001404	ARANESP 200 MCG/ML VIAL
55513001501	ARANESP 300 MCG/ML VIAL
55513002101	ARANESP 40 MCG/0.4 ML
55513002104	ARANESP 40 MCG/0.4 ML
55513002301	ARANESP 60 MCG/0.3 ML
55513002304	ARANESP 60 MCG/0.3 ML
55513002501	ARANESP 100 MCG/0.5 ML
55513002504	ARANESP 100 MCG/0.5 ML
55513002701	ARANESP 150 MCG/0.3 ML
55513002704	ARANESP 150 MCG/0.3 ML
55513002801	ARANESP 200 MCG/0.4 ML
55513003201	ARANESP 500 MCG/1 ML
55513003701	ARANESP 40 MCG/0.4 ML
55513003704	ARANESP 40 MCG/0.4 ML
55513003901	ARANESP 60 MCG/0.3 ML
55513003904	ARANESP 60 MCG/0.3 ML
55513004101	ARANESP 100 MCG/0.5 ML
55513004104	ARANESP 100 MCG/0.5 ML
55513004301	ARANESP 150 MCG/0.3 ML
55513004304	ARANESP 150 MCG/0.3 ML
55513004401	ARANESP 200 MCG/0.4 ML
55513004601	ARANESP 300 MCG/0.6 ML
55513004801	ARANESP 500 MCG/1 ML
55513005301	ARANESP 150 MCG/0.75 ML
55513005304	ARANESP 150 MCG/0.75 ML
55513005401	ARANESP 150 MCG/0.75 ML
55513005404	ARANESP 150 MCG/0.75 ML
55513005701	ARANESP 25 MCG/0.42 ML
55513005704	ARANESP 25 MCG/0.42 ML
55513005801	ARANESP 25 MCG/0.42 ML
55513005804	ARANESP 25 MCG/0.42 ML
55513009001	ARANESP 25 MCG/0.42 ML
55513009101	ARANESP 40 MCG/0.4 ML
55513009201	ARANESP 60 MCG/0.3 ML
55513009301	ARANESP 100 MCG/0.5 ML
55513009401	ARANESP 150 MCG/0.3 ML
55513009501	ARANESP 200 MCG/0.4 ML
55513009601	ARANESP 300 MCG/0.6 ML
55513009701	ARANESP 500 MCG/1 ML
55513011001	ARANESP 300 MCG/ML VIAL
55513011101	ARANESP 300 MCG/0.6 ML

PROCEDURE CODE	PROCEDURE DESCRIPTION
J0881	INJECTION DARBEPOETIN ALFA 1 MICROGRAM (NON-ESRD USE)
J0882	INJECTION DARBEPOETIN ALFA 1 MICROGRAM (FOR ESRD ON DIALYSIS)
Q4054	INJECTION DARBEPOETIN ALFA 1 MCG (FOR ESRD ON DIALYSIS)
J0880	INJECTION DARBEPOETIN ALFA 5 MCG
Q0137	INJECTION DARBEPOETIN ALFA 1 MCG (NON-ESRD USE)

EXHIBIT B

FDA Approved: 11-19-08

Aranesp®
(darbepoetin alfa)
For Injection

WARNINGS: INCREASED MORTALITY, SERIOUS CARDIOVASCULAR and THROMBOEMBOLIC EVENTS, and INCREASED RISK OF TUMOR PROGRESSION OR RECURRENCE

Renal failure: **Patients experienced greater risks for death and serious cardiovascular events when administered erythropoiesis-stimulating agents (ESAs) to target higher versus lower hemoglobin levels (13.5 vs. 11.3 g/dL; 14 vs. 10 g/dL) in two clinical studies. Individualize dosing to achieve and maintain hemoglobin levels within the range of 10 to 12 g/dL.**

Cancer:

- **ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in some clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers (see WARNINGS: Table 1).**
- **To decrease these risks, as well as the risk of serious cardio- and thrombovascular events, use the lowest dose needed to avoid red blood cell transfusion.**
- **Use ESAs only for treatment of anemia due to concomitant myelosuppressive chemotherapy.**
- **ESAs are not indicated for patients receiving myelosuppressive therapy when the anticipated outcome is cure.**
- **Discontinue following the completion of a chemotherapy course.**

(See WARNINGS: Increased Mortality, Serious Cardiovascular and Thromboembolic Events, WARNINGS: Increased Mortality and/or Increased Risk of Tumor Progression or Recurrence, INDICATIONS AND USAGE, and DOSAGE AND ADMINISTRATION.)

DESCRIPTION

Aranesp® is an erythropoiesis stimulating protein, closely related to erythropoietin, that is produced in Chinese hamster ovary (CHO) cells by recombinant DNA technology. Aranesp® is a 165-amino acid protein that differs from recombinant human erythropoietin in containing 5 N-linked oligosaccharide chains, whereas recombinant human erythropoietin contains 3 chains.[1] The two additional N-glycosylation sites result from amino acid substitutions in the erythropoietin peptide backbone. The additional carbohydrate chains increase the approximate molecular weight of the glycoprotein from 30,000 to 37,000 daltons. Aranesp® is formulated as a sterile, colorless, preservative-free protein solution for intravenous or subcutaneous administration.

Single-dose vials are available containing 25, 40, 60, 100, 150, 200, 300, or 500 mcg of Aranesp®.

Single-dose prefilled syringes and prefilled SureClick™ autoinjectors are available containing 25, 40, 60, 100, 150, 200, 300, or 500 mcg of Aranesp®. Each prefilled syringe is equipped with a needle guard that covers the needle during disposal.

Single-dose vials, prefilled syringes and autoinjectors are available in two formulations that contain excipients as follows:

Polysorbate solution Each 1 mL contains 0.05 mg polysorbate 80, and is formulated at pH 6.2 ± 0.2 with 2.12 mg sodium phosphate monobasic monohydrate, 0.66 mg sodium phosphate dibasic anhydrous, and 8.18 mg sodium chloride in Water for Injection, USP (to 1 mL).

Albumin solution Each 1 mL contains 2.5 mg albumin (human), and is formulated at pH 6.0 ± 0.3 with 2.23 mg sodium phosphate monobasic monohydrate, 0.53 mg sodium phosphate dibasic anhydrous, and 8.18 mg sodium chloride in Water for Injection, USP (to 1 mL).

CLINICAL PHARMACOLOGY

Mechanism of Action

Aranesp® stimulates erythropoiesis by the same mechanism as endogenous erythropoietin. A primary growth factor for erythroid development, erythropoietin is produced in the kidney and released into the bloodstream in response to hypoxia. In responding to hypoxia, erythropoietin interacts with progenitor stem cells to increase red blood cell (RBC) production. Production of endogenous erythropoietin is impaired in patients with chronic renal failure (CRF), and erythropoietin deficiency is the primary cause of their anemia. Increased hemoglobin levels are not generally observed until 2 to 6 weeks after initiating treatment with Aranesp® (see **DOSAGE AND ADMINISTRATION**). In patients with cancer receiving concomitant chemotherapy, the etiology of anemia is multifactorial.

Pharmacokinetics

Adult Patients

The pharmacokinetics of Aranesp® were studied in patients with CRF receiving or not receiving dialysis and cancer patients receiving chemotherapy.

Following intravenous administration in CRF patients receiving dialysis, Aranesp® serum concentration-time profiles were biphasic, with a distribution half-life of approximately 1.4 hours and a mean terminal half-life of 21 hours. The terminal half-life of Aranesp® was approximately 3-fold longer than that of Epoetin alfa when administered intravenously.

Following subcutaneous administration of Aranesp® to CRF patients (receiving or not receiving dialysis), absorption was slow and peak concentrations occurred at 48 hours (range: 12 to 72 hours). In CRF patients receiving dialysis, the average half-life was 46 hours (range: 12 to 89 hours), and in CRF patients not receiving dialysis, the average half-life was 70 hours (range: 35 to 139 hours). Aranesp® apparent clearance was approximately 1.4 times faster on average in patients receiving dialysis compared to patients not receiving dialysis. The bioavailability of Aranesp® in CRF patients receiving dialysis after subcutaneous administration was 37% (range: 30% to 50%).

Following the first subcutaneous dose of 6.75 mcg/kg (equivalent to 500 mcg for a 74-kg patient) in patients with cancer, the mean terminal half-life was 74 hours (range: 24 to 144 hours). Peak concentrations were observed at 90 hours (range: 71 to 123 hours) after a dose of 2.25 mcg/kg, and 71 hours (range: 28 to 120 hours) after a dose of 6.75 mcg/kg. When administered on a once every 3 week schedule, 48-hour post-dose Aranesp® levels after the fourth dose were similar to those after the first dose.

Over the dose range of 0.45 to 4.5 mcg/kg Aranesp® administered intravenously or subcutaneously on a once weekly schedule and 4.5 to 15 mcg/kg administered subcutaneously on a once every 3 week schedule, systemic exposure was approximately proportional to dose. No evidence of accumulation was observed beyond an expected < 2-fold increase in blood levels when compared to the initial dose.

Pediatric Patients

Aranesp® pharmacokinetics were studied in 12 pediatric CRF patients (age 3-16 years) receiving or not receiving dialysis. Following a single intravenous or subcutaneous Aranesp® dose, Cmax and half-life were similar to those obtained in adult CRF patients on dialysis. Following a single subcutaneous dose, the average bioavailability was 54% (range: 32% to 70%), which was higher than that obtained in adult CRF patients on dialysis.

CLINICAL STUDIES

Throughout this section of the package insert, the Aranesp® study numbers associated with the nephrology and cancer clinical programs are designated with the letters "N" and "C", respectively.

Chronic Renal Failure Patients

The safety and effectiveness of Aranesp® have been assessed in a number of multicenter studies. Two studies evaluated the safety and efficacy of Aranesp® for the correction of anemia in adult patients with CRF, and three studies (2 in adults and 1 in pediatric patients) assessed the ability of Aranesp® to maintain hemoglobin concentrations in patients with CRF who had been receiving other recombinant erythropoietins.

De Novo Use of Aranesp®

Once Weekly Aranesp® Starting Dose

In two open-label studies, Aranesp® or Epoetin alfa was administered for the correction of anemia in CRF patients who had not been receiving prior treatment with exogenous erythropoietin. Study N1 evaluated CRF patients receiving dialysis; Study N2 evaluated patients not requiring dialysis. In both studies, the starting dose of Aranesp® was 0.45 mcg/kg administered once weekly. The starting dose of Epoetin alfa was 50 Units/kg 3 times weekly in Study N1 and 50 Units/kg twice weekly in Study N2. When necessary, dosage adjustments were instituted to maintain hemoglobin in the study target range of 11 to 13 g/dL. (Note: The recommended hemoglobin target is lower than the target range of these studies. See **DOSAGE AND ADMINISTRATION** for recommended clinical hemoglobin target.) The primary efficacy endpoint was the proportion of patients who experienced at least a 1 g/dL increase in hemoglobin concentration to a level of at least 11 g/dL by 20 weeks (Study N1) or 24 weeks (Study N2). The studies were designed to assess the safety and effectiveness of Aranesp® but not to support conclusions regarding comparisons between the two products.

In Study N1, the hemoglobin target was achieved by 72% (95% CI: 62%, 81%) of the 90 patients treated with Aranesp® and 84% (95% CI: 66%, 95%) of the 31 patients treated with Epoetin alfa. The mean increase in hemoglobin over the initial 4 weeks of Aranesp® treatment was 1.1 g/dL (95% CI: 0.82 g/dL, 1.37 g/dL).

In Study N2, the primary efficacy endpoint was achieved by 93% (95% CI: 87%, 97%) of the 129 patients treated with Aranesp® and 92% (95% CI: 78%, 98%) of the 37 patients treated with Epoetin alfa. The mean increase in hemoglobin from baseline through the initial 4 weeks of Aranesp® treatment was 1.38 g/dL (95% CI: 1.21 g/dL, 1.55 g/dL).

Once Every 2 Week Aranesp® Starting Dose

In two single arm studies (N3 and N4), Aranesp® was administered for the correction of anemia in CRF patients not receiving dialysis. In both studies, the starting dose of Aranesp® was 0.75 mcg/kg administered once every 2 weeks.

In Study N3 (study duration of 18 weeks), the hemoglobin goal (hemoglobin concentration ≥ 11 g/dL) was achieved by 92% (95% CI: 86%, 96%) of the 128 patients treated with Aranesp®.

In Study N4 (study duration of 24 weeks), the hemoglobin goal (hemoglobin concentration of 11-13 g/dL) was achieved by 85% (95% CI: 77%, 93%) of the 75 patients treated with Aranesp®.

Conversion From Other Recombinant Erythropoietins

Two adult studies (N5 and N6) and one pediatric study (N7) were conducted in patients with CRF who had been receiving other recombinant erythropoietins. The studies compared the abilities of Aranesp® and other erythropoietins to maintain hemoglobin concentrations within a study target range of 9 to 13 g/dL in adults and 10 to 12.5 g/dL in pediatric patients. (Note: The recommended hemoglobin target is lower than the target range of these studies. See **DOSAGE AND ADMINISTRATION** for recommended clinical hemoglobin target.) CRF patients who had been receiving stable doses of other recombinant erythropoietins were randomized to Aranesp®, or to continue with their prior erythropoietin at the previous dose and schedule. For patients randomized to Aranesp®, the initial weekly dose was determined on the basis of the previous total weekly dose of recombinant erythropoietin.

Adult Patients

Study N5 was a double-blind study conducted in North America, in which 169 hemodialysis patients were randomized to treatment with Aranesp® and 338 patients continued on Epoetin alfa. Study N6 was an open-label study conducted in Europe and Australia in which 347 patients were randomized to treatment with Aranesp® and 175 patients were randomized to continue on Epoetin alfa or Epoetin beta. Of the 347 patients randomized to Aranesp®, 92% were receiving hemodialysis and 8% were receiving peritoneal dialysis.

In Study N5, a median weekly dose of 0.53 mcg/kg Aranesp® (25th, 75th percentiles: 0.30, 0.93 mcg/kg) was required to maintain hemoglobin in the study target range. In Study N6, a median weekly dose of 0.41 mcg/kg Aranesp® (25th, 75th percentiles: 0.26, 0.65 mcg/kg) was required to maintain hemoglobin in the study target range.

Pediatric Patients

Study N7 was an open-label, randomized study, conducted in the United States in pediatric patients from 1 to 18 years of age with CRF receiving or not receiving dialysis. Patients that were stable on Epoetin alfa were randomized to receive either darbepoetin alfa (n = 82) administered once weekly (subcutaneously or intravenously) or to continue receiving Epoetin alfa (n = 42) at the current dose, schedule, and route of administration. A median weekly dose of 0.41 mcg/kg Aranesp® (25th, 75th percentiles: 0.25, 0.82 mcg/kg) was required to maintain hemoglobin in the study target range.

Cancer Patients Receiving Chemotherapy

Efficacy in patients with anemia due to concomitant chemotherapy was demonstrated based on reduction in the requirement for RBC transfusions.

Once Weekly Dosing

The safety and effectiveness of Aranesp® in reducing the requirement for RBC transfusions in patients undergoing chemotherapy was assessed in a randomized, placebo-controlled, double-blind, multinational study (C1). This study was conducted in anemic (Hgb ≤ 11 g/dL) patients with advanced, small cell or non-small cell lung cancer, who received a platinum-containing chemotherapy regimen. Patients were randomized to receive Aranesp® 2.25 mcg/kg (n = 156) or placebo (n = 158) administered as a single weekly SC injection for up to 12 weeks. The dose was escalated to 4.5 mcg/kg/week at week 6, in subjects with an inadequate response to treatment, defined as less than 1 g/dL hemoglobin increase. There were 67 patients in the Aranesp® arm who had their dose increased from 2.25 to 4.5 mcg/kg/week, at any time during the treatment period.

Efficacy was determined by a reduction in the proportion of patients who were transfused over the 12-week treatment period. A significantly lower proportion of patients in the Aranesp® arm, 26% (95% CI: 20%, 33%) required transfusion compared to 60% (95% CI: 52%, 68%) in the placebo arm (Kaplan-Meier estimate of proportion; $p < 0.001$ by Cochran–Mantel-Haenszel test). Of the 67 patients who received a dose increase, 28% had a 2 g/dL increase in hemoglobin over baseline, generally occurring between weeks 8 to 13. Of the 89 patients who did not receive a dose increase, 69% had a 2 g/dL increase in

hemoglobin over baseline, generally occurring between weeks 6 to 13. On-study deaths occurred in 14% (22/156) of patients treated with Aranesp® and 12% (19/158) of the placebo-treated patients.

Once Every 3 Week Dosing

The safety and effectiveness of once every 3 week Aranesp® therapy in reducing the requirement for red blood cell (RBC) transfusions in patients undergoing chemotherapy was assessed in a randomized, double-blind, multinational study (C2). This study was conducted in anemic (Hgb < 11 g/dL) patients with non-myeloid malignancies receiving multicycle chemotherapy. Patients were randomized to receive Aranesp® at 500 mcg once every 3 weeks (n = 353) or 2.25 mcg/kg (n = 352) administered weekly as a subcutaneous injection for up to 15 weeks. In both groups, the dose was reduced by 40% of the previous dose (e.g., for first dose reduction, to 300 mcg in the once every 3 week group and 1.35 mcg/kg in the once weekly group) if hemoglobin increased by more than 1 g/dL in a 14-day period. Study drug was withheld if hemoglobin exceeded 13 g/dL. In the once every 3 week group, 254 patients (72%) required dose reductions (median time to first reduction at 6 weeks). In the once weekly group, 263 patients (75%) required dose reductions (median time to first reduction at 5 weeks).

Efficacy was determined by a comparison of the Kaplan-Meier estimates of the proportion of patients who received at least one RBC transfusion between day 29 and the end of treatment. Three hundred thirty-five patients in the once every 3 week group and 337 patients in the once weekly group remained on study through or beyond day 29 and were evaluated for efficacy. Twenty-seven percent (95% CI: 22%, 32%) of patients in the once every 3 week group and 34% (95% CI: 29%, 39%) in the weekly group required a RBC transfusion. The observed difference in the transfusion rates (once every 3 week-once weekly) was -6.7% (95% CI: -13.8%, 0.4%).

INDICATIONS AND USAGE

Anemia With Chronic Renal Failure

Aranesp® is indicated for the treatment of anemia associated with chronic renal failure, including patients on dialysis and patients not on dialysis.

Anemia With Non-Myeloid Malignancies Due to Chemotherapy

Aranesp® is indicated for the treatment of anemia due to the effect of concomitantly administered chemotherapy based on studies that have shown a reduction in the need for RBC transfusions in patients with metastatic, non-myeloid malignancies. Studies to determine whether Aranesp® increases mortality or decreases progression-free/recurrence-free survival are ongoing.

- Aranesp® is not indicated for use in patients receiving hormonal agents, therapeutic biologic products, or radiotherapy unless receiving concomitant myelosuppressive chemotherapy.
- Aranesp® is not indicated for patients receiving myelosuppressive therapy when the anticipated outcome is cure due to the absence of studies that adequately characterize the impact of Aranesp® on progression-free and overall survival (see **WARNINGS: Increased Mortality and/or Increased Risk of Tumor Progression or Recurrence**).
- Aranesp® use has not been demonstrated in controlled clinical trials to improve symptoms of anemia, quality of life, fatigue, or patient well-being.

CONTRAINDICATIONS

Aranesp® is contraindicated in patients with:

- uncontrolled hypertension
- known hypersensitivity to the active substance or any of the excipients

WARNINGS

Increased Mortality, Serious Cardiovascular and Thromboembolic Events

Patients with chronic renal failure experienced greater risks for death and serious cardiovascular events when administered erythropoiesis-stimulating agents (ESAs) to target higher versus lower hemoglobin levels (13.5 vs. 11.3 g/dL; 14 vs. 10 g/dL) in two clinical studies. Patients with chronic renal failure and an insufficient hemoglobin response to ESA therapy may be at even greater risk for cardiovascular events and mortality than other patients. Aranesp® and other ESAs increased the risks for death and serious cardiovascular events in controlled clinical trials of patients with cancer. These events included myocardial infarction, stroke, congestive heart failure, and hemodialysis vascular access thrombosis. A rate of hemoglobin rise of > 1 g/dL over 2 weeks may contribute to these risks.

In a randomized prospective trial, 1432 anemic chronic renal failure patients who were not undergoing dialysis were assigned to Epoetin alfa (rHuEPO) treatment targeting a maintenance hemoglobin concentration of 13.5 g/dL or 11.3 g/dL. A major cardiovascular event (death, myocardial infarction, stroke, or hospitalization for congestive heart failure) occurred among 125 (18%) of the 715 patients in the higher hemoglobin group compared to 97 (14%) among the 717 patients in the lower hemoglobin group [Hazard Ratio (HR) 1.3, 95% CI: 1.0, 1.7, p = 0.03].[2]

Increased risk for serious cardiovascular events was also reported from a randomized, prospective trial of 1265 hemodialysis patients with clinically evident cardiac disease (ischemic heart disease or congestive heart failure). In this trial, patients were assigned to Epoetin alfa treatment targeted to a maintenance hemoglobin of either 14 ± 1 g/dL or 10 ± 1 g/dL.[3] Higher mortality (35% vs. 29%) was observed in the 634 patients randomized to a target hemoglobin of 14 g/dL than in the 631 patients assigned a target hemoglobin of 10 g/dL. The reason for the increased mortality observed in this study is unknown; however, the incidence of nonfatal myocardial infarction, vascular access thrombosis, and other thrombotic events was also higher in the group randomized to a target hemoglobin of 14 g/dL.

An increased incidence of thrombotic events has also been observed in patients with cancer treated with erythropoietic agents. In patients with cancer who received Aranesp®, pulmonary emboli, thrombophlebitis, and thrombosis occurred more frequently than in placebo controls (see **ADVERSE REACTIONS: *Cancer Patients Receiving Chemotherapy*, Table 5**).

In a randomized controlled study (referred to as Cancer Study 1 - the 'BEST' study) with another ESA in 939 women with metastatic breast cancer receiving chemotherapy, patients received either weekly Epoetin alfa or placebo for up to a year. This study was designed to show that survival was superior when an ESA was administered to prevent anemia (maintain hemoglobin levels between 12 and 14 g/dL or hematocrit between 36% and 42%). The study was terminated prematurely when interim results demonstrated that a higher mortality at 4 months (8.7% vs. 3.4%) and a higher rate of fatal thrombotic events (1.1% vs. 0.2%) in the first 4 months of the study were observed among patients treated with Epoetin alfa. Based on Kaplan-Meier estimates, at the time of study termination, the 12-month survival was lower in the Epoetin alfa group than in the placebo group (70% vs. 76%; HR 1.37, 95% CI: 1.07, 1.75, p = 0.012).[4]

A systematic review of 57 randomized controlled trials (including Cancer Studies 1 and 5 - the 'BEST' and 'ENHANCE' studies) evaluating 9353 patients with cancer compared ESAs plus RBC transfusion with RBC transfusion alone for prophylaxis or treatment of anemia in cancer patients with or without concurrent antineoplastic therapy. An increased relative risk (RR) of thromboembolic events (RR 1.67, 95% CI: 1.35, 2.06; 35 trials and 6769 patients) was observed in ESA-treated patients. An overall survival hazard ratio of 1.08 (95% CI: 0.99, 1.18; 42 trials and 8167 patients) was observed in ESA-treated patients.[5]

An increased incidence of deep vein thrombosis (DVT) in patients receiving Epoetin alfa undergoing surgical orthopedic procedures has been observed. In a randomized controlled study (referred to as the 'SPINE' study), 681 adult patients, not receiving prophylactic anticoagulation and undergoing spinal surgery, received Epoetin alfa and standard of care (SOC) treatment, or SOC treatment alone.

Preliminary analysis showed a higher incidence of DVT, determined by either Color Flow Duplex Imaging or by clinical symptoms, in the Epoetin alfa group [16 patients (4.7%)] compared to the SOC group [7 patients (2.1%)]. In addition, 12 patients in the Epoetin alfa group and 7 patients in the SOC group had other thrombotic vascular events.

Increased mortality was observed in a randomized placebo-controlled study of Epoetin alfa in adult patients who were undergoing coronary artery bypass surgery (7 deaths in 126 patients randomized to Epoetin alfa versus no deaths among 56 patients receiving placebo). Four of these deaths occurred during the period of study drug administration and all four deaths were associated with thrombotic events.

Aranesp® is not approved for reduction in allogeneic RBC transfusions in patients scheduled for surgical procedures.

Increased Mortality and/or Increased Risk of Tumor Progression or Recurrence

Erythropoiesis-stimulating agents resulted in decreased locoregional control/progression-free survival and/or overall survival (see Table 1). These findings were observed in studies of patients with advanced head and neck cancer receiving radiation therapy (Cancer Studies 5 and 6), in patients receiving chemotherapy for metastatic breast cancer (Cancer Study 1) or lymphoid malignancy (Cancer Study 2), and in patients with non-small cell lung cancer or various malignancies who were not receiving chemotherapy or radiotherapy (Cancer Studies 7 and 8).

Table 1: Randomized, Controlled Trials with Decreased Survival and/or Decreased Locoregional Control

Study / Tumor / (n)	Hemoglobin Target	Achieved Hemoglobin (Median Q1,Q3)	Primary Endpoint	Adverse Outcome for ESA-containing Arm
Chemotherapy				
Cancer Study 1 Metastatic breast cancer (n=939)	12-14 g/dL	12.9 g/dL 12.2, 13.3 g/dL	12-month overall survival	Decreased 12-month survival
Cancer Study 2 Lymphoid malignancy (n=344)	13-15 g/dL (M) 13-14 g/dL (F)	11.0 g/dL 9.8, 12.1 g/dL	Proportion of patients achieving a hemoglobin response	Decreased overall survival
Cancer Study 3 Early breast cancer (n=733)	12.5-13 g/dL	13.1 g/dL 12.5, 13.7 g/dL	Relapse-free and overall survival	Decreased 3 yr. relapse-free and overall survival
Cancer Study 4 Cervical Cancer (n=114)	12-14 g/dL	12.7 g/dL 12.1, 13.3 g/dL	Progression-free and overall survival and locoregional control	Decreased 3 yr. progression-free and overall survival and locoregional control
Radiotherapy Alone				
Cancer Study 5 Head and neck cancer (n=351)	≥15 g/dL (M) ≥14 g/dL (F)	Not available	Locoregional progression-free survival	Decreased 5-year locoregional progression-free survival Decreased overall survival

Cancer Study 6 Head and neck cancer (n=522)	14-15.5 g/dL	Not available	Locoregional disease control	Decreased locoregional disease control
No Chemotherapy or Radiotherapy				
Cancer Study 7 Non-small cell lung cancer (n=70)	12-14 g/dL	Not available	Quality of life	Decreased overall survival
Cancer Study 8 Non-myeloid malignancy (n=989)	12-13 g/dL	10.6 g/dL 9.4, 11.8 g/dL	RBC transfusions	Decreased overall survival

Decreased overall survival:

Cancer Study 1 (the 'BEST' study) was previously described (see **WARNINGS: Increased Mortality, Serious Cardiovascular and Thromboembolic Events**). Mortality at 4 months (8.7% vs. 3.4%) was significantly higher in the Epoetin alfa arm. The most common investigator-attributed cause of death within the first 4 months was disease progression; 28 of 41 deaths in the Epoetin alfa arm and 13 of 16 deaths in the placebo arm were attributed to disease progression. Investigator assessed time to tumor progression was not different between the two groups. Survival at 12 months was significantly lower in the Epoetin alfa arm (70% vs. 76%, HR 1.37, 95% CI: 1.07, 1.75; p = 0.012).[4]

Cancer Study 2 was a Phase 3, double-blind, randomized (Aranesp® vs. placebo) study conducted in 344 anemic patients with lymphoid malignancy receiving chemotherapy. With a median follow-up of 29 months, overall mortality rates were significantly higher among patients randomized to Aranesp® as compared to placebo (HR 1.36, 95% CI: 1.02, 1.82).

Cancer Study 7 was a Phase 3, multicenter, randomized (Epoetin alfa vs. placebo), double-blind study, in which patients with advanced non-small cell lung cancer receiving only palliative radiotherapy or no active therapy were treated with Epoetin alfa to achieve and maintain hemoglobin levels between 12 and 14 g/dL. Following an interim analysis of 70 of 300 patients planned, a significant difference in survival in favor of the patients on the placebo arm of the trial was observed (median survival 63 vs. 129 days; HR 1.84; p = 0.04).

Cancer Study 8 was a Phase 3, double-blind, randomized (Aranesp® vs. placebo), 16-week study in 989 anemic patients with active malignant disease, neither receiving nor planning to receive chemotherapy or radiation therapy. There was no evidence of a statistically significant reduction in proportion of patients receiving RBC transfusions. The median survival was shorter in the Aranesp® treatment group (8 months) compared with the placebo group (10.8 months); HR 1.30, 95% CI: 1.07, 1.57.

Decreased progression-free survival and overall survival:

Cancer Study 3 (the 'PREPARE' study) was a randomized controlled study in which Aranesp® was administered to prevent anemia conducted in 733 women receiving neo-adjuvant breast cancer treatment. After a median follow-up of approximately 3 years the survival rate (86% vs. 90%, HR 1.42, 95% CI: 0.93, 2.18) and relapse-free survival rate were lower (72% vs. 78%, HR 1.33, 95% CI: 0.99, 1.79) in the Aranesp®-treated arm compared to the control arm.

Cancer Study 4 (protocol GOG 191) was a randomized controlled study that enrolled 114 of a planned 460 cervical cancer patients receiving chemotherapy and radiotherapy. Patients were randomized to receive Epoetin alfa to maintain hemoglobin between 12 and 14 g/dL or to transfusion support as needed.

The study was terminated prematurely due to an increase in thromboembolic events in Epoetin alfa-treated patients compared to control (19% vs. 9%). Both local recurrence (21% vs. 20%) and distant recurrence (12% vs. 7%) were more frequent in Epoetin alfa-treated patients compared to control. Progression-free survival at 3 years was lower in the Epoetin alfa-treated group compared to control (59% vs. 62%, HR 1.06, 95% CI: 0.58, 1.91). Overall survival at 3 years was lower in the Epoetin alfa-treated group compared to control (61% vs. 71%, HR 1.28, 95% CI: 0.68, 2.42).

Cancer Study 5 (the 'ENHANCE' study) was a randomized controlled study in 351 head and neck cancer patients where Epoetin beta or placebo was administered to achieve target hemoglobins of 14 and 15 g/dL for women and men, respectively. Locoregional progression-free survival was significantly shorter in patients receiving Epoetin beta (HR 1.62, 95% CI: 1.22, 2.14, p = 0.0008) with a median of 406 days Epoetin beta vs. 745 days placebo. Overall survival was significantly shorter in patients receiving Epoetin beta (HR 1.39, 95% CI: 1.05, 1.84; p = 0.02).

Decreased locoregional control:

Cancer Study 6 (DAHANCA 10) was conducted in 522 patients with primary squamous cell carcinoma of the head and neck receiving radiation therapy randomized to Aranesp® with radiotherapy or radiotherapy alone. An interim analysis on 484 patients demonstrated that locoregional control at 5 years was significantly shorter in patients receiving Aranesp® (RR 1.44, 95% CI: 1.06, 1.96; p = 0.02). Overall survival was shorter in patients receiving Aranesp® (RR 1.28, 95% CI: 0.98, 1.68; p = 0.08).

Hypertension

Patients with uncontrolled hypertension should not be treated with Aranesp®; blood pressure should be controlled adequately before initiation of therapy. Blood pressure may rise during treatment of anemia with Aranesp® or Epoetin alfa. In Aranesp® clinical trials, approximately 40% of patients with CRF required initiation or intensification of antihypertensive therapy during the early phase of treatment when the hemoglobin was increasing. Hypertensive encephalopathy and seizures have been observed in patients with CRF treated with Aranesp® or Epoetin alfa.

Special care should be taken to closely monitor and control blood pressure in patients treated with Aranesp®. During Aranesp® therapy, patients should be advised of the importance of compliance with antihypertensive therapy and dietary restrictions. If blood pressure is difficult to control by pharmacologic or dietary measures, the dose of Aranesp® should be reduced or withheld (see **DOSAGE AND ADMINISTRATION**). A clinically significant decrease in hemoglobin may not be observed for several weeks.

Seizures

Seizures have occurred in patients with CRF participating in clinical trials of Aranesp® and Epoetin alfa. During the first several months of therapy, blood pressure and the presence of premonitory neurologic symptoms should be monitored closely. While the relationship between seizures and the rate of rise of hemoglobin is uncertain, it is recommended that the dose of Aranesp® be decreased if the hemoglobin increase exceeds 1 g/dL in any 2-week period.

Pure Red Cell Aplasia

Cases of pure red cell aplasia (PRCA) and of severe anemia, with or without other cytopenias, associated with neutralizing antibodies to erythropoietin have been reported in patients treated with Aranesp®. This has been reported predominantly in patients with CRF receiving Aranesp® by subcutaneous administration. Any patient who develops a sudden loss of response to Aranesp®, accompanied by severe anemia and low reticulocyte count, should be evaluated for the etiology of loss of effect, including the presence of neutralizing antibodies to erythropoietin (see **PRECAUTIONS: Lack or Loss of Response to Aranesp®**). If anti-erythropoietin antibody-associated anemia is suspected, withhold Aranesp® and other erythropoietic proteins. Contact Amgen (1-800-77AMGEN) to perform assays for binding and neutralizing antibodies. Aranesp® should be permanently discontinued in patients with antibody-mediated anemia. Patients should not be switched to other erythropoietic proteins as antibodies may cross-react (see **ADVERSE REACTIONS: Immunogenicity**).

Albumin (Human)

Aranesp® is supplied in two formulations with different excipients, one containing polysorbate 80 and another containing albumin (human), a derivative of human blood (see **DESCRIPTION**). Based on effective donor screening and product manufacturing processes, Aranesp® formulated with albumin carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

PRECAUTIONS

General

The safety and efficacy of Aranesp® therapy have not been established in patients with underlying hematologic diseases (e.g., hemolytic anemia, sickle cell anemia, thalassemia, porphyria).

The needle cover of the prefilled syringe contains dry natural rubber (a derivative of latex), which may cause allergic reactions in individuals sensitive to latex.

Lack or Loss of Response to Aranesp®

A lack of response or failure to maintain a hemoglobin response with Aranesp® doses within the recommended dosing range should prompt a search for causative factors. Deficiencies of folic acid, iron, or vitamin B_{12} should be excluded or corrected. Depending on the clinical setting, intercurrent infections, inflammatory or malignant processes, osteofibrosis cystica, occult blood loss, hemolysis, severe aluminum toxicity, and bone marrow fibrosis may compromise an erythropoietic response. In the absence of another etiology, the patient should be evaluated for evidence of PRCA and sera should be tested for the presence of antibodies to erythropoietin (see **WARNINGS: Pure Red Cell Aplasia**). See **DOSAGE AND ADMINISTRATION: *Chronic Renal Failure Patients*, Dose Adjustment** for management of patients with an insufficient hemoglobin response to Aranesp® therapy.

Hematology

Sufficient time should be allowed to determine a patient's responsiveness to a dosage of Aranesp® before adjusting the dose. Because of the time required for erythropoiesis and the RBC half-life, an interval of 2 to 6 weeks may occur between the time of a dose adjustment (initiation, increase, decrease, or discontinuation) and a significant change in hemoglobin.

In order to prevent the hemoglobin from exceeding the recommended target range (10 to 12 g/dL) or rising too rapidly (greater than 1 g/dL in 2 weeks), the guidelines for dose and frequency of dose adjustments should be followed (see **WARNINGS** and **DOSAGE AND ADMINISTRATION**).

Allergic Reactions

There have been rare reports of potentially serious allergic reactions, including skin rash and urticaria, associated with Aranesp®. Symptoms have recurred with rechallenge, suggesting a causal relationship exists in some instances. If a serious allergic or anaphylactic reaction occurs, Aranesp® should be immediately and permanently discontinued and appropriate therapy should be administered.

Patients with CRF Not Requiring Dialysis

Patients with CRF not yet requiring dialysis may require lower maintenance doses of Aranesp® than patients receiving dialysis. Though CRF patients not on dialysis generally receive less frequent monitoring of blood pressure and laboratory parameters than dialysis patients, CRF patients not on dialysis may be more responsive to the effects of Aranesp®, and require judicious monitoring of blood pressure and hemoglobin. Renal function and fluid and electrolyte balance should also be closely monitored.

Patients Transitioning to Dialysis

During the transition period onto dialysis, hemoglobin and blood pressure should be monitored carefully and patients may need to have their maintenance doses adjusted to maintain hemoglobin levels within the range of 10 to 12 g/dL (see **DOSAGE AND ADMINISTRATION: Maintenance Dose**).

Dialysis Management

Therapy with Aranesp® results in an increase in RBCs and a decrease in plasma volume, which could reduce dialysis efficiency; patients who are marginally dialyzed may require adjustments in their dialysis prescription.

Laboratory Tests

After initiation of Aranesp® therapy, the hemoglobin should be determined weekly until it has stabilized and the maintenance dose has been established (see **DOSAGE AND ADMINISTRATION**). After a dose adjustment, the hemoglobin should be determined weekly for at least 4 weeks, until it has been determined that the hemoglobin has stabilized in response to the dose change. The hemoglobin should then be monitored at regular intervals.

In order to ensure effective erythropoiesis, iron status should be evaluated for all patients before and during treatment, as the majority of patients will eventually require supplemental iron therapy. Supplemental iron therapy is recommended for all patients whose serum ferritin is below 100 mcg/L or whose serum transferrin saturation is below 20%.

Information for Patients

Patients should be informed of the increased risks of mortality, serious cardiovascular events, thromboembolic events, and increased risk of tumor progression or recurrence (see **WARNINGS**). Patients should be informed of the possible side effects of Aranesp® and be instructed to report them to the prescribing physician. Patients should be informed of the signs and symptoms of allergic drug reactions and be advised of appropriate actions. Patients should be counseled on the importance of compliance with their Aranesp® treatment, dietary and dialysis prescriptions, and the importance of judicious monitoring of blood pressure and hemoglobin concentration should be stressed.

In those rare cases where it is determined that a patient can safely and effectively administer Aranesp® at home, appropriate instruction on the proper use of Aranesp® should be provided for patients and their caregivers. Patients should be instructed to read the Aranesp® Medication Guide and Patient Instructions for Use and should be informed that the Medication Guide is not a disclosure of all possible side effects. Patients and caregivers should also be cautioned against the reuse of needles, syringes, prefilled SureClick™ autoinjectors, or drug product, and be thoroughly instructed in their proper disposal. A puncture-resistant container for the disposal of used syringes, autoinjectors, and needles should be made available to the patient. Patients should be informed that the needle cover on the prefilled syringe contains dry natural rubber (a derivative of latex), which should not be handled by persons sensitive to latex.

Drug Interactions

No formal drug interaction studies of Aranesp® have been performed.

Carcinogenesis, Mutagenesis, and Impairment of Fertility

Carcinogenicity: The carcinogenic potential of Aranesp® has not been evaluated in long-term animal studies. Aranesp® did not alter the proliferative response of non-hematological cells in vitro or in vivo. In toxicity studies of approximately 6 months duration in rats and dogs, no tumorigenic or unexpected mitogenic responses were observed in any tissue type. Using a panel of human tissues, the in vitro tissue binding profile of Aranesp® was identical to Epoetin alfa. Neither molecule bound to human tissues other than those expressing the erythropoietin receptor.

Mutagenicity: Aranesp® was negative in the in vitro bacterial and CHO cell assays to detect mutagenicity and in the in vivo mouse micronucleus assay to detect clastogenicity.

Impairment of Fertility: When administered intravenously to male and female rats prior to and during mating, reproductive performance, fertility, and sperm assessment parameters were not affected at any doses evaluated (up to 10 mcg/kg/dose, administered 3 times weekly). An increase in post implantation fetal loss was seen at doses equal to or greater than 0.5 mcg/kg/dose, administered 3 times weekly.

Pregnancy Category C

When Aranesp® was administered intravenously to rats and rabbits during gestation, no evidence of a direct embryotoxic, fetotoxic, or teratogenic outcome was observed at doses up to 20 mcg/kg/day. The only adverse effect observed was a slight reduction in fetal weight, which occurred at doses causing exaggerated pharmacological effects in the dams (1 mcg/kg/day and higher). No deleterious effects on uterine implantation were seen in either species. No significant placental transfer of Aranesp® was observed in rats. An increase in post implantation fetal loss was observed in studies assessing fertility (see **PRECAUTIONS: Carcinogenesis, Mutagenesis, and Impairment of Fertility: Impairment of Fertility**).

Intravenous injection of Aranesp® to female rats every other day from day 6 of gestation through day 23 of lactation at doses of 2.5 mcg/kg/dose and higher resulted in offspring (F1 generation) with decreased body weights, which correlated with a low incidence of deaths, as well as delayed eye opening and delayed preputial separation. No adverse effects were seen in the F2 offspring.

There are no adequate and well-controlled studies in pregnant women. Aranesp® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

It is not known whether Aranesp® is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Aranesp® is administered to a nursing woman.

Pediatric Use

Pediatric CRF Patients

A study of the conversion from Epoetin alfa to Aranesp® among pediatric CRF patients over 1 year of age showed similar safety and efficacy to the findings from adult conversion studies (see **CLINICAL PHARMACOLOGY** and **CLINICAL STUDIES**). Safety and efficacy in the initial treatment of anemic pediatric CRF patients or in the conversion from another erythropoietin to Aranesp® in pediatric CRF patients less than 1 year of age have not been established.

Pediatric Cancer Patients

The safety and efficacy of Aranesp® in pediatric cancer patients have not been established.

Geriatric Use

Of the 1801 CRF patients in clinical studies of Aranesp®, 44% were age 65 and over, while 17% were age 75 and over. Of the 873 cancer patients in clinical studies receiving Aranesp® and concomitant chemotherapy, 45% were age 65 and over, while 14% were age 75 and over. No overall differences in safety or efficacy were observed between older and younger patients.

ADVERSE REACTIONS

General

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of Aranesp® cannot be directly compared to rates in the clinical trials of other drugs and may not reflect the rates observed in practice.

Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. Neutralizing antibodies to erythropoietin, in association with PRCA or severe anemia (with or without other cytopenias), have been reported in patients receiving Aranesp® (see **WARNINGS: Pure Red Cell Aplasia**) during post-marketing experience.

In clinical studies, the percentage of patients with antibodies to Aranesp® was examined using the BIAcore assay. Sera from 1501 CRF patients and 1159 cancer patients were tested. At baseline, prior to Aranesp® treatment, binding antibodies were detected in 59 (4%) of CRF patients and 36 (3%) of cancer patients. While receiving Aranesp® therapy (range 22-177 weeks), a follow-up sample was taken. One

additional CRF patient and eight additional cancer patients developed antibodies capable of binding Aranesp®. None of the patients had antibodies capable of neutralizing the activity of Aranesp® or endogenous erythropoietin at baseline or at end of study. No clinical sequelae consistent with PRCA were associated with the presence of these antibodies.

The incidence of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies across products within this class (erythropoietic proteins) may be misleading.

Chronic Renal Failure Patients

Adult Patients

In all studies, the most frequently reported serious adverse events with Aranesp® were infection, congestive heart failure, angina pectoris/cardiac chest pain, thrombosis vascular access, and cardiac arrhythmia/cardiac arrest. The most frequently reported adverse events resulting in clinical intervention (e.g., discontinuation of Aranesp®, adjustment in dosage, or the need for concomitant medication to treat an adverse reaction symptom) were infection, hypertension, hypotension, and muscle spasm. See **WARNINGS: Increased Mortality, Serious Cardiovascular and Thromboembolic Events** and **Hypertension**.

The data described below reflect exposure to Aranesp® in 1801 CRF patients, including 675 exposed for at least 6 months, of whom 185 were exposed for greater than 1 year. Aranesp® was evaluated in active-controlled (n = 823) and uncontrolled studies (n = 978). These data include a pooled analysis of CRF patients not on dialysis and dialysis patients who were studied for the correction of anemia and maintenance of hemoglobin.

The population encompassed an age range from 18 to 94 years. Fifty-five percent of the patients were male. The percentages of Caucasian, Black, Asian, and Hispanic patients were 80%, 13%, 3%, and 2%, respectively. The median weekly dose of Aranesp® for patients who received either once weekly or once every 2 week administration was 0.44 mcg/kg (25th, 75th percentiles: 0.30, 0.64 mcg/kg).

Some of the adverse events reported are typically associated with CRF, or recognized complications of dialysis, and may not necessarily be attributable to Aranesp® therapy. No important differences in adverse event rates between treatment groups were observed in controlled studies in which patients received Aranesp® or other recombinant erythropoietins.

The data in Table 2 reflect those adverse events occurring in at least 5% of patients treated with Aranesp®.

Table 2. Adverse Events Occurring in ≥ 5% of CRF Patients

Event	Patients Treated with Aranesp® (n = 1801)
APPLICATION SITE	
Injection Site Pain	6%
BODY AS A WHOLE	
Peripheral Edema	10%
Fatigue	9%
Fever	7%
Death	6%
Chest Pain, Unspecified	7%
Fluid Overload	6%
Access Infection	6%
Influenza-like Symptoms	6%
Access Hemorrhage	7%
Asthenia	5%
CARDIOVASCULAR	
Hypertension	20%
Hypotension	20%
Cardiac Arrhythmias/Cardiac Arrest	8%
Angina Pectoris/Cardiac Chest Pain	8%
Thrombosis Vascular Access	6%
Congestive Heart Failure	5%
CNS/PNS	
Headache	15%
Dizziness	7%
GASTROINTESTINAL	
Diarrhea	14%
Vomiting	14%
Nausea	11%
Abdominal Pain	10%
Constipation	5%
MUSCULO-SKELETAL	
Muscle Spasm	17%
Arthralgia	9%
Limb Pain	8%
Back Pain	7%

(Continued)

Table 2. Adverse Events Occurring in ≥ 5% of CRF Patients (Continued)

Event	Patients Treated with Aranesp® (n = 1801)
RESISTANCE MECHANISM	
Infection[a]	24%
RESPIRATORY	
Upper Respiratory Infection	15%
Dyspnea	10%
Cough	9%
Bronchitis	5%
SKIN AND APPENDAGES	
Pruritus	6%

[a] Infection includes sepsis, bacteremia, pneumonia, peritonitis, and abscess.

The incidence rates for other clinically significant events are shown in Table 3.

Table 3. Percent Incidence of Other Clinically Significant Events in CRF Patients

Event	Patients Treated with Aranesp® (n = 1801)
Acute Myocardial Infarction	2%
Stroke	2%
Seizure	1%
Transient Ischemic Attack	≤1%

Pediatric Patients

In Study N7, Aranesp® was administered to 81 pediatric CRF patients who had stable hemoglobin concentrations while previously receiving Epoetin alfa (see **CLINICAL STUDIES**). In this study, the most frequently reported serious adverse events with Aranesp® were catheter sepsis, fever, catheter related infection, chronic renal failure, and vascular access complication. The most commonly reported adverse events were fever, headache, nasopharyngitis, hypertension, hypotension, injection site pain, cough, peritonitis, and vomiting. Aranesp® administration was discontinued because of injection site pain in two patients and moderate hypertension in a third patient.

Studies have not evaluated the effects of Aranesp® when administered to pediatric patients as the initial treatment for the anemia associated with CRF.

Thrombotic Events

Vascular access thrombosis in hemodialysis patients occurred in clinical trials at an annualized rate of 0.22 events per patient year of Aranesp® therapy. Rates of thrombotic events (e.g., vascular access thrombosis, venous thrombosis, and pulmonary emboli) with Aranesp® therapy were similar to those observed with other recombinant erythropoietins in these trials; the median duration of exposure was 12 weeks.

Cancer Patients Receiving Chemotherapy

The incidence data described below reflect the exposure to Aranesp® in 873 cancer patients including patients exposed to Aranesp® once weekly (547, 63%), once every 2 weeks (128, 16%), and once every 3 weeks (198, 23%). Aranesp® was evaluated in seven studies that were active-controlled and/or placebo-controlled studies of up to 6 months duration. The Aranesp®-treated patient demographics were as follows: median age of 63 years (range of 20 to 91 years); 40% male; 88% Caucasian, 5% Hispanic,

4% Black, and 3% Asian. Over 90% of patients had locally advanced or metastatic cancer, with the remainder having early stage disease. Patients with solid tumors (e.g., lung, breast, colon, ovarian cancers) and lymphoproliferative malignancies (e.g., lymphoma, multiple myeloma) were enrolled in the clinical studies. All of the 873 Aranesp®-treated subjects also received concomitant cyclic chemotherapy.

The most frequently reported serious adverse events included death (10%), fever (4%), pneumonia (3%), dehydration (3%), vomiting (2%), and dyspnea (2%). The most commonly reported adverse events were fatigue, edema, nausea, vomiting, diarrhea, fever, and dyspnea (see **Table 4**). Except for those events listed in Tables 4 and 5, the incidence of adverse events in clinical studies occurred at a similar rate compared with patients who received placebo and were generally consistent with the underlying disease and its treatment with chemotherapy. The most frequently reported reasons for discontinuation of Aranesp® were progressive disease, death, discontinuation of the chemotherapy, asthenia, dyspnea, pneumonia, and gastrointestinal hemorrhage. No important differences in adverse event rates between treatment groups were observed in controlled studies in which patients received Aranesp® or other recombinant erythropoietins.

Table 4. Adverse Events Occurring in ≥ 5% of Patients Receiving Chemotherapy

Event	Aranesp® (n = 873)	Placebo (n = 221)
BODY AS A WHOLE		
Fatigue	33%	30%
Edema	21%	10%
Fever	19%	16%
CNS/PNS		
Dizziness	14%	8%
Headache	12%	9%
GASTROINTESTINAL		
Diarrhea	22%	12%
Constipation	18%	17%
METABOLIC/NUTRITION		
Dehydration	5%	3%
MUSCULO-SKELETAL		
Arthralgia	13%	6%
Myalgia	8%	5%
SKIN AND APPENDAGES		
Rash	7%	3%

Table 5. Incidence of Other Clinically Significant Adverse Events in Patients Receiving Chemotherapy

Event	All Aranesp® (n = 873)	Placebo (n = 221)
Hypertension	3.7%	3.2%
Seizures/Convulsions[a]	0.6%	0.5%
Thrombotic Events	6.2%	4.1%
Pulmonary Embolism	1.3%	0.0%
Thrombosis[b]	5.6%	4.1%

[a] Seizures/Convulsions include the preferred terms: Convulsions, Convulsions Grand Mal, and Convulsions Local.

[b] Thrombosis includes: Thrombophlebitis, Thrombophlebitis Deep, Thrombosis Venous, Thrombosis Venous Deep, Thromboembolism, and Thrombosis.

In a randomized controlled trial of Aranesp® 500 mcg once every 3 weeks (n = 353) and Aranesp® 2.25 mcg/kg once weekly (n = 352), the incidences of all adverse events and of serious adverse events were similar between the two groups.

Thrombotic and Cardiovascular Events

Overall, the incidence of thrombotic events was 6.2% for Aranesp® and 4.1% for placebo. However, the following events were reported more frequently in Aranesp®-treated patients than in placebo controls: pulmonary embolism, thromboembolism, thrombosis, and thrombophlebitis (deep and/or superficial). In addition, edema of any type was more frequently reported in Aranesp®-treated patients (21%) than in patients who received placebo (10%).

OVERDOSAGE

The expected manifestations of Aranesp® overdosage include signs and symptoms associated with an excessive and/or rapid increase in hemoglobin concentration, including any of the cardiovascular events described in **WARNINGS** and listed in **ADVERSE REACTIONS**. Patients receiving an overdosage of Aranesp® should be monitored closely for cardiovascular events and hematologic abnormalities. Polycythemia should be managed acutely with phlebotomy, as clinically indicated. Following resolution of the effects due to Aranesp® overdosage, reintroduction of Aranesp® therapy should be accompanied by close monitoring for evidence of rapid increases in hemoglobin concentration (> 1 g/dL in any 2-week period). In patients with an excessive hematopoietic response, reduce the Aranesp® dose in accordance with the recommendations described in **DOSAGE AND ADMINISTRATION**.

DOSAGE AND ADMINISTRATION

IMPORTANT: See BOXED WARNINGS and WARNINGS: Increased Mortality, Serious Cardiovascular and Thromboembolic Events.

Aranesp® is supplied in vials or in prefilled syringes with UltraSafe® Needle Guards*. Following administration of Aranesp® from the prefilled syringe, the UltraSafe® Needle Guard should be activated to prevent accidental needlesticks.

Aranesp® is also supplied in prefilled SureClick™ autoinjectors containing the same dosage strengths as the prefilled syringes. Because the autoinjectors are designed to deliver the full content, autoinjectors should only be used for patients who need the full dose. If the required dose is not available in an autoinjector, prefilled syringes, or vials should be used to administer the required dose. Autoinjectors are for subcutaneous administration only.

Chronic Renal Failure Patients

Aranesp® may be administered either intravenously or subcutaneously as a single weekly injection. ***In patients on hemodialysis, the intravenous route is recommended.*** The dose should be started and slowly adjusted as described below based on hemoglobin levels. If a patient fails to respond or maintain a response, this should be evaluated (see **WARNINGS: Pure Red Cell Aplasia, PRECAUTIONS: Lack or Loss of Response to Aranesp®** and **PRECAUTIONS: Laboratory Tests**). When Aranesp® therapy is initiated or adjusted, the hemoglobin should be followed weekly until stabilized and monitored at least monthly thereafter. During therapy, hematological parameters should be monitored regularly. Doses must be individualized to ensure that hemoglobin is maintained at an appropriate level for each patient.

For patients who respond to Aranesp® with a rapid increase in hemoglobin (e.g., more than 1 g/dL in any 2-week period), the dose of Aranesp® should be reduced.

Individualize dosing to achieve and maintain hemoglobin levels within the range of 10 to 12 g/dL.

Starting Dose

Correction of Anemia

The initial dose by subcutaneous or intravenous administration is 0.45 mcg/kg body weight, as a single injection once weekly. Alternatively, in patients not receiving dialysis, an initial dose of 0.75 mcg/kg may be administered subcutaneously as a single injection once every 2 weeks. If hemoglobin excursions outside the recommended range occur, the Aranesp® dose should be adjusted as described below.

The use of Aranesp® in pediatric CRF patients as the initial treatment to correct anemia has not been studied.

Maintenance Dose

The dose should be individualized to maintain hemoglobin levels within the range of 10 to 12 g/dL (see **Dose Adjustment**). If hemoglobin excursions outside the recommended range occur, the Aranesp® dose should be adjusted as described below. For many patients, the appropriate maintenance dose will be lower than the starting dose. CRF patients not on dialysis, in particular, may require lower maintenance doses. In the maintenance phase, Aranesp® may continue to be administered as a single injection once weekly or once every 2 weeks.

Dose Adjustment

The dose should be adjusted for each patient to achieve and maintain hemoglobin levels within the range of 10 to 12 g/dL. If hemoglobin excursions outside the recommended range occur, the Aranesp® dose should be adjusted as described below. Increases in dose should not be made more frequently than once a month.

If the hemoglobin is increasing and approaching 12 g/dL, the dose should be reduced by approximately 25%. If the hemoglobin continues to increase, doses should be temporarily withheld until the hemoglobin begins to decrease, at which point therapy should be reinitiated at a dose approximately 25% below the previous dose. If the hemoglobin increases by more than 1 g/dL in a 2-week period, the dose should be decreased by approximately 25%.

If the increase in hemoglobin is less than 1 g/dL over 4 weeks and iron stores are adequate (see **PRECAUTIONS: Laboratory Tests**), the dose of Aranesp® may be increased by approximately 25% of the previous dose. Further increases may be made at 4-week intervals until the specified hemoglobin is obtained.

For patients whose hemoglobin does not attain a level within the range of 10 to 12 g/dL despite the use of appropriate Aranesp® dose titrations over a 12-week period:

- do not administer higher Aranesp® doses and use the lowest dose that will maintain a hemoglobin level sufficient to avoid the need for recurrent RBC transfusions,
- evaluate and treat for other causes of anemia (see **PRECAUTIONS: Lack or Loss of Response to Aranesp®**), and

- thereafter, hemoglobin should continue to be monitored and if responsiveness improves, Aranesp® dose adjustments should be made as described above; discontinue Aranesp® if responsiveness does not improve and the patient needs recurrent RBC transfusions.

Conversion From Epoetin alfa to Aranesp®

The starting weekly dose of Aranesp® for adults and pediatric patients should be estimated on the basis of the weekly Epoetin alfa dose at the time of substitution (see **Table 6**). For pediatric patients receiving a weekly Epoetin alfa dose of < 1,500 units/week, the available data are insufficient to determine an Aranesp® conversion dose. Because of variability, doses should be titrated to achieve and maintain hemoglobin levels within the range of 10 to 12 g/dL. Due to the longer serum half-life, Aranesp® should be administered less frequently than Epoetin alfa. Aranesp® should be administered once a week if a patient was receiving Epoetin alfa 2 to 3 times weekly. Aranesp® should be administered once every 2 weeks if a patient was receiving Epoetin alfa once per week. The route of administration (intravenous or subcutaneous) should be maintained.

Table 6. Estimated Aranesp® Starting Doses (mcg/week) for Patients Based on Previous Epoetin alfa Dose (Units/week)

Previous Weekly Epoetin alfa Dose (Units/week)	Weekly Aranesp® Dose (mcg/week)	
	Adult	Pediatric
< 1,500	6.25	See text*
1,500 to 2,499	6.25	6.25
2,500 to 4,999	12.5	10
5,000 to 10,999	25	20
11,000 to 17,999	40	40
18,000 to 33,999	60	60
34,000 to 89,999	100	100
≥ 90,000	200	200

*For pediatric patients receiving a weekly Epoetin alfa dose of < 1,500 units/week, the available data are insufficient to determine an Aranesp® conversion dose.

Cancer Patients Receiving Chemotherapy

For pediatric patients, see **PRECAUTIONS: Pediatric Use**.

The recommended starting dose for Aranesp® administered weekly is 2.25 mcg/kg as a subcutaneous injection.

The recommended starting dose for Aranesp® administered once every 3 weeks is 500 mcg as a subcutaneous injection.

Therapy should not be initiated at hemoglobin levels ≥ 10 g/dL. For both dosing schedules, the dose should be adjusted for each patient to maintain the lowest hemoglobin level sufficient to avoid RBC transfusion. If the rate of hemoglobin increase is more than 1 g/dL per 2-week period or when the hemoglobin reaches a level needed to avoid transfusion, the dose should be reduced by 40% of the previous dose. If the hemoglobin exceeds a level needed to avoid transfusion, Aranesp® should be

temporarily withheld until the hemoglobin approaches a level where transfusions may be required. At this point, therapy should be reinitiated at a dose 40% below the previous dose.

For patients receiving weekly administration, if there is less than a 1 g/dL increase in hemoglobin after 6 weeks of therapy, the dose of Aranesp® should be increased up to 4.5 mcg/kg.

Discontinue Aranesp® if after 8 weeks of therapy there is no response as measured by hemoglobin levels or if transfusions are still required.

Discontinue Aranesp® following the completion of a chemotherapy course (see **BOXED WARNINGS: *Cancer***).

Preparation and Administration of Aranesp®

Do not shake Aranesp® or leave vials, syringes, or prefilled SureClick™ autoinjectors exposed to light. After removing the vials, prefilled syringes, or autoinjectors from the refrigerator, protect from room light until administration. Vigorous shaking or exposure to light may denature Aranesp®, causing it to become biologically inactive. Always store vials, prefilled syringes, or autoinjectors of Aranesp® in their carton until use.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Do not use any vials, prefilled syringes, or autoinjectors exhibiting particulate matter or discoloration.

Do not dilute Aranesp®.

Do not administer Aranesp® in conjunction with other drug solutions.

Aranesp® contains no preservatives. Discard any unused portion. **Do not pool unused portions from the vials or prefilled syringes. Do not use the vial, prefilled syringe, or autoinjector more than one time.**

Following administration of Aranesp® from the prefilled syringe, activate the UltraSafe® Needle Guard. Place your hands behind the needle, grasp the guard with one hand, and slide the guard forward until the needle is completely covered and the guard clicks into place. NOTE: If an audible click is not heard, the needle guard may not be completely activated.

The prefilled SureClick™ autoinjector is designed to deliver the full dose. The completion of the injection is signaled by an audible click. Removal of the autoinjector from the injection site automatically extends a needle cover.

The autoinjectors, the syringes used with vials, and the entire prefilled syringe with activated needle guard should be disposed of in a puncture-proof container.

See the accompanying "Patient Instructions for Use" insert for complete instructions on the preparation and administration of Aranesp® for patients, including injection site selection.

HOW SUPPLIED

Aranesp® is available in single-dose vials in two solutions, an albumin solution and a polysorbate solution. The words "Albumin Free" appear on the polysorbate container labels and the package main panels as well as other panels as space permits. Aranesp® single-dose prefilled syringes and prefilled SureClick™ autoinjectors are available in albumin and polysorbate solutions. Both prefilled syringes and autoinjectors are supplied with a 27-gauge, ½-inch needle.

Each prefilled syringe is equipped with an UltraSafe® Needle Guard that is manually activated to cover the needle during disposal. The needle cover of the prefilled syringe contains dry natural rubber (a derivative of latex). The autoinjector has a needle cover that automatically extends as the autoinjector is removed from the injection site after completion of the injection.

Aranesp® is available in the following packages:

Single-dose Vial, Polysorbate Solution

1 Vial/Pack, 4 Packs/Case	4 Vials/Pack, 4 Packs/Case	4 Vials/Pack, 10 Packs/Case
200 mcg/1 mL (NDC 55513-006-01)	200 mcg/1 mL (NDC 55513-006-04)	25 mcg/1 mL (NDC 55513-002-04)
300 mcg/1 mL (NDC 55513-110-01)	300 mcg/1 mL (NDC 55513-110-04)	40 mcg/1 mL (NDC 55513-003-04)
500 mcg/1 mL (NDC 55513-008-01)		60 mcg/1 mL (NDC 55513-004-04)
		100 mcg/1 mL (NDC 55513-005-04)
		150 mcg/0.75 mL (NDC 55513-053-04)

Single-dose Vial, Albumin Solution

1 Vial/Pack, 4 Packs/Case	4 Vials/Pack, 4 Packs/Case	4 Vials/Pack, 10 Packs/Case
200 mcg/1 mL (NDC 55513-014-01)	200 mcg/1 mL (NDC 55513-014-04)	25 mcg/1 mL (NDC 55513-010-04)
300 mcg/1 mL (NDC 55513-015-01)	300 mcg/1 mL (NDC 55513-015-04)	40 mcg/1 mL (NDC 55513-011-04)
500 mcg/1 mL (NDC 55513-016-01)		60 mcg/1 mL (NDC 55513-012-04)
		100 mcg/1 mL (NDC 55513-013-04)
		150 mcg/0.75 mL (NDC 55513-054-04)

Single-dose Prefilled Syringe (SingleJect®) with a 27-gauge, ½-inch needle with an UltraSafe® Needle Guard, Polysorbate Solution

1 Syringe/Pack, 4 Packs/Case	4 Syringes/Pack, 4 Packs/Case	4 Syringes/Pack, 10 Packs/Case
200 mcg/0.4 mL (NDC 55513-028-01)	200 mcg/0.4 mL (NDC 55513-028-04)	25 mcg/0.42 mL (NDC 55513-057-04)
300 mcg/0.6 mL (NDC 55513-111-01)	300 mcg/0.6 mL (NDC 55513-111-04)	40 mcg/0.4 mL (NDC 55513-021-04)
500 mcg/1 mL (NDC 55513-032-01)		60 mcg/0.3 mL (NDC 55513-023-04)
		100 mcg/0.5 mL (NDC 55513-025-04)
		150 mcg/0.3 mL (NDC 55513-027-04)

Single-dose Prefilled Syringe (SingleJect®) with a 27-gauge, ½-inch needle with an UltraSafe® Needle Guard, Albumin Solution

1 Syringe/Pack, 4 Packs/Case	4 Syringes/Pack, 4 Packs/Case	4 Syringes/Pack, 10 Packs/Case
200 mcg/0.4 mL (NDC 55513-044-01)	200 mcg/0.4 mL (NDC 55513-044-04)	25 mcg/0.42 mL (NDC 55513-058-04)
300 mcg/0.6 mL (NDC 55513-046-01)	300 mcg/0.6 mL (NDC 55513-046-04)	40 mcg/0.4 mL (NDC 55513-037-04)
500 mcg/1 mL (NDC 55513-048-01)		60 mcg/0.3 mL (NDC 55513-039-04)
		100 mcg/0.5 mL (NDC 55513-041-04)
		150 mcg/0.3 mL (NDC 55513-043-04)

Single-dose Prefilled SureClick™ Autoinjector with a 27-gauge, ½-inch needle, Polysorbate Solution

1 Autoinjector/Pack

25 mcg/0.42 mL
(NDC 55513-090-01)

40 mcg/0.4 mL
(NDC 55513-091-01)

60 mcg/0.3 mL

(NDC 55513-092-01)

100 mcg/0.5 mL
(NDC 55513-093-01)

150 mcg/0.3 mL
(NDC 55513-094-01)

200 mcg/0.4 mL
(NDC 55513-095-01)

300 mcg/0.6 mL
(NDC 55513-096-01)

500 mcg/1 mL
(NDC 55513-097-01)

Single-dose Prefilled SureClick™ Autoinjector with a 27-gauge, ½-inch needle, Albumin Solution

1 Autoinjector/Pack

25 mcg/0.42 mL
(NDC 55513-080-01)

40 mcg/0.4 mL
(NDC 55513-081-01)

60 mcg/0.3 mL
(NDC 55513-082-01)

100 mcg/0.5 mL
(NDC 55513-083-01)

150 mcg/0.3 mL
(NDC 55513-084-01)

200 mcg/0.4 mL
(NDC 55513-085-01)

300 mcg/0.6 mL
(NDC 55513-086-01)

500 mcg/1 mL
(NDC 55513-087-01)

Storage

Store at 2° to 8°C (36° to 46°F). Do not freeze or shake. Protect from light.

REFERENCES

1. Egrie JC, Browne JK. Development and characterization of novel erythropoiesis stimulating protein (NESP). *Br J Cancer.* 2001; 84 (suppl 1): 3-10.
2. Singh AK, Szczech L, Tang KL, et al. Correction of Anemia with Epoetin Alfa in Chronic Kidney Disease. *N Engl J Med.* 2006; 355: 2085-98.
3. Besarab A, Bolton WK, Browne JK, et al. The effects of normal as compared with low hematocrit values in patients with cardiac disease who are receiving hemodialysis and epoetin. *N Engl J Med.* 1998; 339: 584-590.
4. Leyland-Jones B, Semiglazov V, Pawlicki M, et al. Maintaining Normal Hemoglobin Levels With Epoetin Alfa in Mainly Nonanemic Patients With Metastatic Breast Cancer Receiving First-Line Chemotherapy: A Survival Study. *JCO.* 2005; 23(25): 1-13.
5. Bohlius J, Wilson J, Seidenfeld J, et al. Recombinant Human Erythropoietins and Cancer Patients: Updated Meta-Analysis of 57 Studies Including 9353 Patients. *J Natl Cancer Inst.* 2006; 98: 708-14.

Rx only

This product, or its use, may be covered by one or more US Patents, including US Patent No. 5,618,698, in addition to others including patents pending.

AMGEN®

Manufactured by:

Amgen Manufacturing, Limited, a subsidiary of Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

* UltraSafe® is a registered trademark of Safety Syringes, Inc.

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EXHIBIT C

		Aranesp	Procrit (1,000 units)
	Enter cumulative monthly dose ==>	120	40
	Enter % off-invoice discount ==>	29.4%	24.5%
Cost	WAP per mcg / unit	$4.446	$12.170
	WAP for current dose	$533.52	$486.80
	WAP minus off-invoice discount %	$376.67	$367.53
	Enter total rebate % ==>	8.0%	8.5%
	Total rebate $$ earned	$30.13	$31.24
	Total Net Cost	$346.53	$336.29
Reimbursement	ASP+ 6% per mcg / unit	$2.989	$9.027
	ASP + 6% for current dose	$358.68	$361.08
	Medicare Payment (80% of ASP + 6%)	$286.94	$288.86
	Net Cost Recovery without Secondary	-$59.59	-$47.43
	Secondary Payment (20%)	$71.74	$72.22
Net	**Total Cost Recovery (with a secondary payment)**	**$12.15**	**$24.79**

		Aranesp	Procrit	Difference
Total Annual Impact on Office	Total patients being treated==>	50	50	
	Net per month per patient	$12.15	$24.79	-$12.64
	Net per year per patient	$145.78	$297.44	-$151.66
	Net for all patients per month	$607.40	$1,239.32	-$631.92
	Net for all patients per year	**$7,288.85**	**$14,871.83**	-$7,582.98

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EXHIBIT D

		Aranesp	Procrit (1,000 units)
	Enter cumulative monthly dose ==>	120	40
	Enter % off-invoice discount ==>	29.4%	24.5%
Cost	WAP per mcg / unit	$4.446	$12.170
	WAP for current dose	$533.52	$486.80
	WAP minus off-invoice discount %	$376.67	$367.53
	Enter total rebate % ==>	8.0%	8.5%
	Total rebate $$ earned	$30.13	$31.24
	Total Net Cost	$346.53	$336.29
Reimbursement	ASP+ 6% per mcg / unit	$3.491	$10.029
	ASP + 6% for current dose	$418.94	$401.16
	Medicare Payment (80% of ASP + 6%)	$335.15	$320.93
	Net Cost Recovery without Secondary	-$11.38	-$15.37
	Secondary Payment (20%)	$83.79	$80.23
Net	**Total Cost Recovery (with a secondary payment)**	**$72.41**	**$64.87**

		Aranesp	Procrit	Difference
Total Annual Impact on Office	Total patients being treated==>	50	50	
	Net per month per patient	$72.41	$64.87	$7.54
	Net per year per patient	$868.88	$778.40	$90.48
	Net for all patients per month	$3,620.32	$3,243.31	$377.00
	Net for all patients per year	**$43,443.80**	**$38,919.76**	$4,524.04

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EXHIBIT E

For Information Only
Aranesp Vs. Procrit and Overfill

Procrit	Units	AWP	Medicare Allowable	80% Primary	20% Secondary
M20, 20,000 1ML	20,000	$267.20	$253.84	$203.07	$50.77
M10, 10,000 2mL	20,000	$267.20	$253.84	$203.07	$50.77
Procrit Overfill					
M20, 20,000 1ML	2280	$29.64	$28.16	$22.53	$5.63
M10, 10,000 2mL	3360	$43.68	$41.50	$33.20	$8.30
Total Units with Overfill					
M20, 20,000 1ML	22,280	$296.84	$282.00	$225.60	$56.40
M10, 10,000 2mL	23,360	$310.88	$295.34	$236.27	$59.07

Aranesp	Mcg	AWP	Medicare Allowable	80% Primary	20% Secondary
25 1mL	25	$124.75	$118.51	$94.81	$23.70
40 1mL	40	$199.60	$189.62	$151.70	$37.92
60 1mL	60	$299.40	$284.43	$227.54	$56.89
100 1mL	100	$499.00	$474.05	$379.24	$94.81
150 1mL	150	$748.50	$711.08	$568.86	$142.22
200 1mL	200	$998.00	$948.10	$758.48	$189.62
300 1mL	300	$1,497.00	$1,422.15	$1,137.72	$284.43

Aranesp with Overfill	Mcg	AWP	Medicare Allowable	80% Primary	20% Secondary
25 1mL	29.2	$145.71	$138.42	$110.74	$27.68
40 1mL	46.72	$233.13	$221.48	$177.18	$44.30
60 1mL	70.08	$349.70	$332.21	$265.77	$66.44
100 1mL	116.8	$582.83	$553.69	$442.95	$110.74
150 1mL	175.2	$874.25	$830.54	$664.43	$166.11
200 1mL	233.6	$1,165.66	$1,107.38	$885.90	$221.48
300 1mL	350.4	$1,748.50	$1,661.07	$1,328.86	$332.21

Practice Cost Revenue Model-For Information Only

DRUG	Doses per Month	# of Patients	AWP	Medicare Allowable	Medicare 80%	Secondary 20%
Aranesp/mcg(+Overfill)						
60	2	1	$299.25	$284.29	$227.43	$56.86
Procrit/1000(+Overfill)						
20	2	1	$307.28	$291.92	$233.53	$58.38

Aranesp Monthly Estimates	
AWP	$598.50
WAP	$478.80

Purchase Price (WAP-7%)	445.28
Medicare 80%	454.86
Difference	$9.58

Secondary 20%	113.72
Difference	123.29

Aranesp Yearly Estimates	
AWP	$7,182.00
WAP	$5,745.60

Purchase Price (WAP 7%)	5,343.41
Medicare 80%	5,458.32
Difference	$114.91

Secondary 20%	1,364.58
Difference	1,479.49

Procrit Monthly Estimates	
AWP	$614.56
WAP	$445.20

Purchase Price (WAP-5%)	422.94
Medicare 80%	467.07
Difference	$44.13

Secondary 20%	116.77
Difference	160.89

Procrit Yearly Estimates	
AWP	$7,374.72
WAP	$5,342.40

Purchase Price (WAP-5%)	5,075.28
Medicare 80%	5,604.79
Difference	$529.51

Secondary 20%	1,401.20
Difference	1,930.70

Procrit Total Units	AWP	AWP + Overfill	Reimbursed
M20, 20,000 1ML	267.12	$296.84	$293.92 (22000 units)
M10, 10,000 2mL	267.12	$310.88	$307.28 (23000 units)

Aranesp		AWP	AWP + Overfill
25	1mL	$124.69	$145.71
40	1mL	$199.50	$233.13
60	1mL	$299.25	$349.70
100	1mL	$498.75	$582.83
150	1mL	$748.50	$874.25
200	1mL	$997.50	$1,165.66
300	1mL	$1,497.00	$1,748.50

For Information Only
Aranesp Vs. Procrit and Overfill

Procrit	Units	AWP	Medicare Allowable	80% Primary	20% Secondary
M20, 20,000 1ML	20,000	$267.20	$253.84	$203.07	$50.77
M10, 10,000 2mL	20,000	$267.20	$253.84	$203.07	$50.77

Total Units with Overfill	Units	Billable Units	AWP	Medicare Allowable	80% Primary	20% Secondary
M20, 20,000 1ML	22,280	22,000	$293.92	$279.22	$223.38	$55.84
M10, 10,000 2mL	23,360	23,000	$307.28	$291.92	$233.53	$58.38

Aranesp	Mcg	AWP	Medicare Allowable	80% Primary	20% Secondary
25 1ml	25	$124.75	$118.51	$94.81	$23.70
40 1mL	40	$199.60	$189.62	$151.70	$37.92
60 1mL	60	$299.40	$284.43	$227.54	$56.89
100 1mL	100	$499.00	$474.05	$379.24	$94.81
150 1mL	150	$748.50	$711.08	$568.86	$142.22
200 1mL	200	$998.00	$948.10	$758.48	$189.62
300 1mL	300	$1,497.00	$1,422.15	$1,137.72	$284.43

Aranesp with Overfill	Mcg	Billable Mcg	AWP	Medicare Allowable	80% Primary	20% Secondary
25 1mL	29.2	25	$124.75	$118.51	$94.81	$23.70
40 1mL	46.72	45	$224.55	$213.32	$170.66	$42.66
60 1mL	70.08	70	$349.30	$331.84	$265.47	$66.37
100 1mL	116.8	115	$573.85	$545.16	$436.13	$109.03
150 1mL	175.2	175	$873.25	$829.59	$663.67	$165.92
200 1mL	233.6	230	$1,147.70	$1,090.32	$872.25	$218.06
300 1mL	350.4	350	$1,746.50	$1,659.18	$1,327.34	$331.84

EXHIBIT F

		Aranesp	Procrit (1,000 units)
	Enter cumulative monthly dose ==>	**120**	**40**
	Enter % off-invoice discount ==>	**0.294**	**0.245**
Cost	WAP per mcg / unit	4.446	12.17
	WAP for current dose	=C6*C3	=D6*D3
	WAP minus off-invoice discount %	=C7*(1-C4)	=D7*(1-D4)
	Enter total rebate % ==>	**0.08**	**0.085**
	Total rebate $$ earned	=C9*C8	=D9*D8
	Total Net Cost	=C8-C10	=D8-D10
Reimbursement	ASP+ 6% per mcg / unit	2.989	9.027
	ASP + 6% for current dose	=C13*C3	=D13*D3
	Medicare Payment (80% of ASP + 6%)	=0.8*C14	=0.8*D14
	Net Cost Recovery without Secondary	=C15-C11	=D15-D11
	Secondary Payment (20%)	=0.2*C14	=0.2*D14
Net	**Total Cost Recovery (with a secondary payment)**	**=C14-C11**	**=D14-D11**

		Aranesp	Procrit	Difference
Total Annual Impact on Office	**Total patients being treated==>**	**50**	**50**	
	Net per month per patient	=C20	=D20	=C29-D29
	Net per year per patient	=C29*12	=D29*12	=C30-D30
	Net for all patients per month	=C28*C29	=D28*D29	=C31-D31
	Net for all patients per year	**=C28*C30**	**=D28*D30**	=C32-D32

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EXHIBIT G

		Aranesp	Procrit (1,000 units)
	Enter cumulative monthly dose ==>	120	40
	Enter % off-invoice discount ==>	0.294	0.245
Cost	WAP per mcg / unit	4.446	12.17
	WAP for current dose	=C6*C3	=D6*D3
	WAP minus off-invoice discount %	=C7*(1-C4)	=D7*(1-D4)
	Enter total rebate % ==>	0.08	0.085
	Total rebate $$ earned	=C9*C8	=D9*D8
	Total Net Cost	=C8-C10	=D8-D10
Reimbursement	ASP+ 6% per mcg / unit	=1.168*2.989	=1.111*9.027
	ASP + 6% for current dose	=C13*C3	=D13*D3
	Medicare Payment (80% of ASP + 6%)	=0.8*C14	=0.8*D14
	Net Cost Recovery without Secondary	=C15-C11	=D15-D11
	Secondary Payment (20%)	=0.2*C14	=0.2*D14
Net	Total Cost Recovery (with a secondary payment)	=C14-C11	=D14-D11

		Aranesp	Procrit	Difference
Total Annual Impact on Office	Total patients being treated==>	50	50	
	Net per month per patient	=C20	=D20	=C29-D29
	Net per year per patient	=C29*12	=D29*12	=C30-D30
	Net for all patients per month	=C28*C29	=D28*D29	=C31-D31
	Net for all patients per year	=C28*C30	=D28*D30	=C32-D32

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EXHIBIT H

Palomar Medical Group

Standard PACT Agreement with 4% from INN (Aranesp WAP $4.23, ASP $3.54.)

60mcg:

	$253.80	
	-10%	
	$228.42	
	-4%	
	$219.28	**Amount Paid**

26% of $228.42 = **$59.39= Rebate**

Reimbursement = $212.40

$219.28	$59.39
($212.40)	($6.88)
$6.88	**$52.51**

100mcg:

	$423.00	
	-10%	
	$380.70	
	-4%	
	$365.47	**Amount Paid**

26% of $380.70 = **$98.98** Rebate

Reimbursement = $354.00

$365.47	$98.98
($354.00)	($11.47)
$11.47	**$87.51**

Procrit - 15% OID, 22% rebate (WAP $11.75 and $11.93, ASP $10.18)

20,000 units at $11.75			20,000 units at $11.93		
	$235.00			$238.60	
	-15%			-15%	
	$199.75	**Amount Paid**		**$202.81**	**Amount Paid**
22% of $199.75 = **$43.95 Rebate**			22% of $202.81=**$44.62 Rebate**		
Reimbursement = $203.60			**Reimbursement = $203.60**		
$203.60- $199.75 = $3.85			$203.60 - $202.81 = .79		
	$43.95			$44.62	
	$3.85			0.79	
	$47.80			**$45.41**	

40,000 units at $11.75			40,000 units at $11.93		
	$470.00			$477.20	
	-15%			-15%	
	$399.50	**Amount Paid**		**$405.62**	**Amount Paid**
22% of $399.50 = **$87.89 Rebate**			22% of $405.62 = **$89.24 Rebate**		
Reimbursement = $407.20			**Reimbursement = $407.20**		
	$407.20	$7.70		$407.20	$1.58
	($399.50)	$87.89		($405.62)	$89.24
	$7.70	**$95.59**		$1.58	**$90.82**

Ramenofsky and Barager

Standard PACT Agreement (Aranesp WAP $4.23, ASP $3.54.) 4.5% from INN

60mcg:

$253.80		
-10%		
$228.42		
-4.50%		
$218.14	**Amount Paid**	

26% of $228.42 = **$59.39= Rebate**

Reimbursement = $212.40

$218.14	$59.39
($212.40)	($5.74)
$5.74	**$53.65**

100mcg:

$423.00		
-10%		
$380.70		
-4.5%		
$363.57	**Amount Paid**	

26% of $380.70 = **$98.98** Rebate

Reimbursement = $354.00

$363.57	$98.98
($354.00)	($9.57)
$9.57	**$89.41**

Procrit - 15% OID, 22% rebate (WAP $11.75 and $11.93, ASP $10.18)

20,000 units at $11.75			20,000 units at $11.93		
	$235.00			$238.60	
	-15%			-15%	
	$199.75	**Amount Paid**		**$202.81**	**Amount Paid**
22% of $199.75 = **$43.95 Rebate**			22% of $202.81=**$44.62 Rebate**		
Reimbursement = $203.60			**Reimbursement = $203.60**		
	$203.60	$43.95		$203.60	$44.62
	($199.75)	$3.85		($202.81)	0.79
	$3.85	**$47.80**		$0.790	**$45.41**

40,000 units at $11.75			40,000 units at $11.93		
	$470.00			$477.20	
	-15%			-15%	
	$399.50	**Amount Paid**		**$405.62**	**Amount Paid**
22% of $399.50 = **$87.89 Rebate**			22% of $405.62 = **$89.24 Rebate**		
Reimbursement = $407.20			**Reimbursement = $407.20**		
	$407.20	$7.70		$407.20	$1.58
	($399.50)	$87.89		($405.62)	$89.24
	$7.70	**$95.59**		$1.58	**$90.82**

Balboa Nephrology Medical Group

Platinum Plus PACT Agreement with 4.5% from INN (WAP $4.23, ASP $3.54)

194mcg			
	$820.62		
	-20%		
	$656.50		
	-4.5%	INN	
	$626.95		
	16.80%	All units	
	$521.62	**Amount Paid**	

18% of $656.50 = **$118.17 Rebate**

Reimbursement = $686.76

$686.76	$165.14
($521.62)	$118.17
$165.14	**$283.31**

Procrit - 20.5% OID, 22% rebate (WAP $11.75 and $11.93, ASP $10.18)
(15% Ortho, 5.5% Matrix)

43,500 units at $11.75			43,500 units at $11.93		
	$511.13			$518.96	
	-15.0%			-15.0%	
	$434.46			$441.11	
	-5.50%	Matrix		-5.50%	
	$410.56			$416.86	
	11.1%	All units		11.1%	All units
	$364.98	**Amount Paid**		**$370.58**	**Amount Paid**
22% of $434.46 = **$95.58 Rebate**			22% of $441.11 = **$97.04 Rebate**		
Reimbursement = $442.83			**Reimbursement = $442.83**		
	$442.83	$77.85		$442.83	$72.25
	($364.98)	$95.58		($370.58)	$97.04
	$77.85	**$173.43**		$72.25	**$169.29**

Balboa Nephrology Medical Group

Platinum Plus PACT Agreement with 4.5% from INN (WAP $4.23, ASP $3.54)

194mcg		
	$820.62	
	-20%	
	$656.50	
	-4.5%	
	$626.95	**Amount Paid**
16% of $656.50 = **$100.31 Rebate**		
Reimbursement = $686.76		
	$686.76	$59.81
	($626.95)	$100.31
	$59.81	**$160.12**

Procrit - 20.5% OID, 22% rebate (WAP $11.75 and $11.93, ASP $10.18)
(15% Ortho, 5.5% Matrix)

43,500 units at $11.75			43,500 units at $11.93		
	$511.13			$518.96	
	-15.0%			-15.0%	
	$434.46			$441.11	
	-5.50%			-5.50%	
	$410.56			$416.86	
	-10%	All units		-10%	All units
	$369.50	**Amount Paid**		**$375.16**	**Amount Paid**
22% of $434.46 = **$95.58 Rebate**			22% of $441.11 = **$97.04 Rebate**		
Reimbursement = $442.83			**Reimbursement = $442.83**		
	$442.83	$73.33		$442.83	$67.67
	($369.50)	$95.58		($375.16)	$97.04
	$73.33	**$168.91**		$67.67	**$164.71**

Balboa Nephrology Medical Group

Platinum Plus PACT Agreement with 4.5% from INN (WAP $4.23, ASP $3.54)

200mcg

	$846.00	
	-20%	
	$676.80	
	-4.5%	
	$646.34	**Amount Paid**

16% of $676.80 = **$108.28 Rebate**

Reimbursement = $708.00

$708.00	$61.66
($646.34)	$108.28
$61.66	**$169.94**

Procrit - 20% OID, 22% rebate (WAP $11.75 and $11.93, ASP $10.18)

40,000 units at $11.75			40,000 units at $11.93		
	$470.00			$477.20	
	-20%			-20%	
	$376.00	**Amount Paid**		**$381.76**	**Amount Paid**
22% of $376.00 = **$82.72 Rebate**			22% of $381.76 = **$83.99 Rebate**		
Reimbursement = $407.20			**Reimbursement = $407.20**		
	$407.20	$31.20		$407.20	$25.44
	($376.00)	$82.72		($381.76)	$83.99
	$31.20	**$113.92**		$25.44	**$109.43**

EXHIBIT I

MEDICARE ENROLLMENT APPLICATION

INSTITUTIONAL PROVIDERS

CMS-855A

SEE PAGE 1 TO DETERMINE IF YOU ARE COMPLETING THE CORRECT APPLICATION

SEE PAGE 2 FOR INFORMATION ON WHERE TO MAIL THIS APPLICATION.

SEE PAGE 41 TO FIND A LIST OF THE SUPPORTING DOCUMENTATION THAT MUST BE SUBMITTED WITH THIS APPLICATION.

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB NO. 0938-0685

WHO SHOULD SUBMIT THIS APPLICATION

The following health care organizations must complete this application to initiate the enrollment process:

Community Mental Health Center
Comprehensive Outpatient Rehabilitation Facility
Critical Access Hospital
End-Stage Renal Disease Facility
Federally Qualified Health Center
Histocompatibility Laboratory
Home Health Agency
Hospice
Hospital
Indian Health Services Facility
Organ Procurement Organization
Outpatient Physical Therapy / Occupational Therapy / Speech Pathology Services
Religious Non-Medical Health Care Institution
Rural Health Clinic
Skilled Nursing Facility

If your provider type is not listed above, contact your designated fee-for-service contractor before you submit this application.

Complete this application if you are a health care organization and you:

- Plan to bill Medicare for Part A medical services, or
- Would like to report a change to your existing Part A enrollment data. A change must be reported within 90 days of the effective date of the change; per 42 C.F.R. 424.520(b), changes of ownership or control must be reported within 30 days of the effective date of the change.

BILLING NUMBER INFORMATION

The NPI is the standard unique health identifier for health care providers and is assigned by the National Plan and Provider Enumeration System (NPPES). **Medicare healthcare providers, except organ procurement organizations, must obtain an NPI prior to enrolling in Medicare or before submitting a change to your existing Medicare enrollment information.** Applying for an NPI is a process separate from Medicare enrollment. To obtain an NPI, you may apply online at *https://NPPES.cms.hhs.gov*. As an organizational health care provider, it is your responsibility to determine if you have "subparts." A subpart is a component of an organization that furnishes healthcare and is not itself a legal entity. If you do have subparts, you must determine if they should obtain their own unique NPIs. Before you complete this enrollment application, you need to make those determinations and obtain NPI(s) accordingly.

IMPORTANT: For NPI purposes, sole proprietors and sole proprietorships are considered to be "Type 1" providers. Organizations (e.g., corporations, partnerships) are treated as "Type 2" entities. When reporting the NPI of a sole proprietor on this application, therefore, the individual's Type 1 NPI should be reported; for organizations, the Type 2 NPI should be furnished.

For more information about subparts, visit *www.cms.hhs.gov/NationalProvIdentStand* to view the "Medicare Expectations Subparts Paper."

The Medicare Identification Number, often referred to as the CMS Certification Number (CCN) or Medicare "legacy" number, is a generic term for any number other than the NPI that is used to identify a Medicare provider.

INSTRUCTIONS FOR COMPLETING AND SUBMITTING THIS APPLICATION

- Type or print all information so that it is legible. Do not use pencil.
- Report additional information within a section by copying and completing that section for each additional entry.
- Attach all required supporting documentation.
- Keep a copy of your completed Medicare enrollment package for your records.
- Send the completed application with original signatures and all required documentation to your designated Medicare fee-for-service contractor.

AVOID DELAYS IN YOUR ENROLLMENT

To avoid delays in the enrollment process, you should:

- Complete all required sections.
- Ensure that the legal business name shown in Section 2 matches the name on the tax documents.
- Ensure that the correspondence address shown in Section 2 is the provider's address.
- Enter your NPI in the applicable sections.
- Enter all applicable dates.
- Ensure that the correct person signs the application.
- Send your application and all supporting documentation to the designated fee-for-service contractor.

OBTAINING MEDICARE APPROVAL

The usual process for becoming a certified Medicare provider is as follows:

1. The applicant completes and submits a CMS-855A enrollment application and all supporting documentation to its fee-for-service contractor.
2. The fee-for-service contractor reviews the application and makes a recommendation for approval or denial to the State survey agency, with a copy to the CMS Regional Office.
3. The State agency conducts a survey. Based on the survey results, the State agency makes a recommendation for approval or denial (a certification of compliance or noncompliance) to the CMS Regional Office. Certain provider types may elect voluntary accreditation by a CMS-recognized accrediting organization in lieu of a State survey.
4. The CMS Regional Office makes the final decision regarding program eligibility. The CMS Regional Office also works with the Office of Civil Rights to obtain necessary Civil Rights clearances. If approved, the provider must typically sign a provider agreement.

ADDITIONAL INFORMATION

For additional information regarding the Medicare enrollment process, visit *www.cms.hhs.gov/MedicareProviderSupEnroll*.

The fee-for-service contractor may request, at any time during the enrollment process, documentation to support or validate information reported on the application. You are responsible for providing this documentation in a timely manner.

The information you provide on this application will not be shared. It is protected under 5 U.S.C. Section 552(b)(4) and/or (b)(6), respectively. For more information, see the last page of this application for the Privacy Act Statement.

MAIL YOUR APPLICATION

The Medicare fee-for-service contractor (also referred to as a fiscal intermediary or a Medicare administrative contractor) that services your State is responsible for processing your enrollment application. To locate the mailing address for your fee-for-service contractor, go to *www.cms.hhs.gov/MedicareProviderSupEnroll*.

SECTION 1: BASIC INFORMATION

NEW ENROLLEES

If you are:

- Enrolling with a particular fee-for-service contractor for the first time.
- Undergoing a change of ownership where the new owner will not be accepting assignment of the Medicare assets and liabilities of the seller/former owner.

ENROLLED MEDICARE PROVIDERS

The following actions apply to Medicare providers already enrolled in the program:

Reactivation

To reactivate your Medicare billing privileges, submit this enrollment application. In addition, you must be able to submit a valid claim and meet all current requirements for your provider type before reactivation can occur.

Voluntary Termination

A provider should voluntarily terminate its Medicare enrollment when:

- It will no longer be rendering services to Medicare patients,
- It is planning to cease (or has ceased) operations,
- There has been an acquisition/merger and the new owner will not be using the identification number of the entity it has acquired,
- There has been a consolidation and the identification numbers of the consolidating providers will no longer be used, or
- There has been a change of ownership and the new owner will not be accepting assignment of the Medicare assets and liabilities of the seller/former owner, meaning that the number of the seller/former owner will no longer be used.

NOTE: A voluntary identification number termination cannot be used to circumvent any corrective action plan or any pending/ongoing investigation, nor can it be used to avoid a period of reasonable assurance, where a provider must operate for a certain period without recurrence of the deficiencies that were the basis for the termination. The provider will not be reinstated until the completion of the reasonable assurance period.

Change of Ownership (CHOW)

A CHOW typically occurs when a Medicare provider has been purchased (or leased) by another organization. The CHOW results in the transfer of the old owner's Medicare Identification Number and provider agreement (including any outstanding Medicare debt of the old owner) to the new owner. The regulatory citation for CHOWs can be found at 42 C.F.R. 489.18. If the purchaser (or lessee) elects not to accept a transfer of the provider agreement, then the old agreement should be terminated and the purchaser or lessee is considered a new applicant.

SECTION 1: BASIC INFORMATION (Continued)

Acquisition/Merger

An acquisition/merger occurs when a currently enrolled Medicare provider is purchasing or has been purchased by another enrolled provider. Only the purchaser's Medicare Identification Number and tax identification number remain.

Acquisitions/mergers are different from CHOWs. In the case of an acquisition/merger, the seller/former owner's Medicare Identification Number dissolves. In a CHOW, the seller/former owner's provider number typically remains intact and is transferred to the new owner.

Consolidation

A consolidation occurs when two or more enrolled Medicare providers consolidate to form a new business entity.

Consolidations are different from acquisitions/mergers. In an acquisition/merger, two entities combine but the Medicare Identification Number and tax identification number (TIN) of the purchasing entity remain intact. In a consolidation, the TINs and Medicare Identification Numbers of the consolidating entities dissolve and a new TIN and Medicare Identification Number are assigned to the new, consolidated entity.

> Because of the various situations in which a CHOW, acquisition/merger, or consolidation can occur, it is recommended that the provider contact its fee-for-service contractor or its CMS Regional Office if it is unsure as to whether such a transaction has occurred. The provider should also review the applicable federal regulation at 42 C.F.R. 489.18 for additional guidance.

Change of Information

A change of information should be submitted if you are changing, adding, or deleting information under your current tax identification number. Changes in your existing enrollment data must be reported to the Medicare fee-for-service contractor in accordance with 42 C.F.R. 424.520(b).

NOTE: Ownership changes that do not qualify as CHOWs, acquisitions/mergers, or consolidations should be reported here. The most common example involves stock transfers. For instance, assume that a business entity's stock is owned by A, B, and C. A sells his stock to D. While this is an ownership change, it is generally not a formal CHOW under 42 C.F.R. 489.18. Thus, the ownership change from A to D should be reported as a change of information, not a CHOW. If you have any questions on whether an ownership change should be reported as a CHOW or a change of information, contact your fee-for-service contractor or CMS Regional Office.

If you are already enrolled in Medicare and are not receiving Medicare payments via EFT, any change to your enrollment information will require you to submit a CMS-588 application. All future payments will then be made via EFT.

Revalidation

CMS may require you to submit or update your enrollment information. The fee-for-service contractor will notify you when it is time for you to revalidate your enrollment information. Do not submit a revalidation application until you have been contacted by the fee-for-service contractor.

SECTION 1: BASIC INFORMATION

A. Check one box and complete the required sections

REASON FOR APPLICATION	BILLING NUMBER INFORMATION	REQUIRED SECTIONS
❑ You are a **new enrollee** in Medicare	Enter your Medicare Identification Number (if issued) and the NPI you would like to link to this number in Section 4.	**Complete all** sections except **2F, 2G,** and **2H**
❑ You are enrolling with another fee-for-service contractor's jurisdiction ❑ You are **reactivating** your Medicare enrollment	Enter your Medicare Identification Number (if issued) and the NPI you would like to link to this number in Section 4.	**Complete all** sections except **2F, 2G,** and **2H**
❑ You are **voluntarily terminating** your Medicare enrollment	Effective Date of Termination: Medicare Identification Number that is terminating *(if issued)*: NPI *(if issued)*:	**Complete sections:** **1, 2B1, 13,** and either **15** or **16**
❑ There has been a **Change of Ownership (CHOW)** of the Medicare-enrolled provider You are the: ❑ Seller/Former Owner ❑ Buyer/New Owner	Medicare Identification Number *(if issued)*: NPI: Tax Identification Number:	**Seller/Former Owner:** **1A, 2F, 13,** and either **15** or **16** **Buyer/New Owner:** **Complete all** sections except **2G** and **2H**
❑ Your organization has taken part in an **Acquisition** or **Merger** You are the: ❑ Seller/Former Owner ❑ Buyer/New Owner	Medicare Identification Number of the Seller/Former Owner *(if issued)*: NPI: Tax Identification Number:	**Seller/Former Owner:** **1A, 2G, 13,** and either **15** or **16** **Buyer/New Owner:** **1A, 2G, 4, 13,** and either **15** (if you are the authorized official) or **16** (if you are the delegated official), and **6** for the signer if that authorized or delegated official has not been established for this provider.
❑ Your organization has **Consolidated** with another organization You are the: ❑ Former organization ❑ New organization	Medicare Identification Number of the Seller/Former Owner *(if issued)*: NPI: Tax Identification Number:	**Former Organizations:** **1A, 2H, 13,** and either **15** or **16** **New Organization:** **Complete all** sections except **2F** and **2G**
❑ You are **changing** your Medicare information	Medicare Identification Number *(if issued)*: NPI:	**Go to Section 1B**
❑ You are **revalidating** your Medicare enrollment	Enter your Medicare Identification Number (if issued) and the NPI you would like to link to this number in Section 4.	**Complete all sections except 2F, 2G, and 2H**

SECTION 1: BASIC INFORMATION (Continued)

B. Check all that apply and complete the required sections:

	REQUIRED SECTIONS
❑ Identifying Information	**1, 2** (complete only those sections that are changing), **3, 13,** and either **15** (if you are the authorized official) **or 16** (if you are the delegated official), and Section 6 for the signer if that authorized or delegated official has not been established for this provider.
❑ Adverse Legal Actions/Convictions	**1, 2B1, 3, 13,** and either **15** (if you are the authorized official) **or 16** (if you are the delegated official), and Section 6 for the signer if that authorized or delegated official has not been established for this provider.
❑ Practice Location Information, Payment Address & Medical Record Storage Information	**1, 2B1, 3, 4** (complete only those sections that are changing), **13,** and either **15** (if you are the authorized official) **or 16** (if you are the delegated official), and Section 6 for the signer if that authorized or delegated official has not been established for this provider.
❑ Ownership Interest and/or Managing Control Information (Organizations)	**1, 2B1, 3, 5, 13,** and either **15** (if you are the authorized official) **or 16** (if you are the delegated official), and Section 6 for the signer if that authorized or delegated official has not been established for this provider.
❑ Ownership Interest and/or Managing Control Information (Individuals)	**1, 2B1, 3, 6, 13,** and either **15** (if you are the authorized official) **or 16** (if you are the delegated official), and Section 6 for the signer if that authorized or delegated official has not been established for this provider.
❑ Chain Home Office Information	**1, 2B1, 3, 7, 13,** and either **15** (if you are the authorized official) **or 16** (if you are the delegated official), and Section 6 for the signer if that authorized or delegated official has not been established for this provider.
❑ Billing Agency Information	**1, 2B1, 3, 8** (complete only those sections that are changing), **13,** and either **15** (if you are the authorized official) **or 16** (if you are the delegated official), and Section 6 for the signer if that authorized or delegated official has not been established for this provider.
❑ Special Requirements for Home Health Agencies	**1, 2B1, 3, 12, 13,** and either **15** (if you are the authorized official) **or 16** (if you are the delegated official), and Section 6 for the signer if that authorized or delegated official has not been established for this provider.
❑ Authorized Official(s)	**1, 2B1, 3, 6, 13,** and **15.**
❑ Delegated Official(s) (Optional)	**1, 2B1, 3, 6, 13, 15,** and **16**.

SECTION 2: IDENTIFYING INFORMATION

NEW ENROLLEES

Submit separate CMS-855A enrollment applications if the types of providers for which this application is being submitted are separately recognized provider types with different rules regarding Medicare participation. For example, if a provider functions as both a hospital and an end-stage renal disease (ESRD) facility, the provider must complete two separate enrollment applications (CMS-855A)—one for the hospital and one for the ESRD facility.

If a hospital performs multiple types of services, only one enrollment application (CMS-855A) is required. For example, a hospital that has a swing-bed unit need only submit one enrollment application (CMS-855A). This is because the provider is operating as a single provider type—a hospital—that happens to have a distinct part furnishing different/additional services.

Special Enrollment Notes

- If you are adding a psychiatric or rehabilitation unit to a hospital, check the appropriate subcategory under the "Hospital" heading. (A separate enrollment for the psychiatric/rehabilitation unit is not required). The unit should be listed as a practice location in Section 4.
- If you are adding a home health agency (HHA) branch, list it as a practice location in Section 4. A separate enrollment application is not necessary.
- If you are changing hospital types (e.g., general hospital to a psychiatric hospital), indicate this in Section 2. A new/separate enrollment is not necessary.
- If you are adding an HHA sub-unit (as opposed to a branch), this requires an initial enrollment application for the sub-unit.
- If the hospital will focus on certain specialized services, the applicant should analyze whether the facility will be a general hospital or will fall under the category of a specialty hospital. A specialty hospital is defined as a facility that is primarily engaged in cardiac, orthopedic, or surgical care. Based upon Diagnosis Related Group/Major Diagnosis Category (DRG/MDC) and type (medical/surgical), the applicant should project all inpatient discharges expected in the first year of the hospital's operation. Those applicants that project that 45% or more of the hospital's inpatient cases will fall in either cardiac (MDC-5), orthopedic (MDC-8), or surgical care should check the Hospital—Specialty Hospital block in Section 2A2.

SECTION 2: IDENTIFYING INFORMATION (Continued)

A. TYPE OF PROVIDER

The provider must meet all Federal and State requirements for the type of provider checked. Check only one provider type. If the provider functions as two or more provider types, a separate enrollment application (CMS-855A) must be submitted for each type.

1. Type of Provider (other than Hospitals—See 2A2). Check only one:

- ❑ Community Mental Health Center
- ❑ Comprehensive Outpatient Rehabilitation Facility
- ❑ Critical Access Hospital
- ❑ End-Stage Renal Disease Facility
- ❑ Federally Qualified Health Center
- ❑ Histocompatibility Laboratory
- ❑ Home Health Agency
- ❑ Home Health Agency (Sub-unit)
- ❑ Hospice
- ❑ Indian Health Services Facility
- ❑ Organ Procurement Organization
- ❑ Outpatient Physical Therapy/Occupational Therapy/ Speech Pathology Services
- ❑ Religious Non-Medical Health Care Institution
- ❑ Rural Health Clinic
- ❑ Skilled Nursing Facility
- ❑ Other (Specify):_____

2. If this provider is a hospital, check all applicable subgroups and units listed below and complete Section 2A3.

- ❑ Hospital—General
- ❑ Hospital—Acute Care
- ❑ Hospital—Children's (excluded from PPS)
- ❑ Hospital—Long-Term (excluded from PPS)
- ❑ Hospital—Psychiatric (excluded from PPS)
- ❑ Hospital—Rehabilitation (excluded from PPS)
- ❑ Hospital—Short-Term (General and Specialty)
- ❑ Hospital—Swing-Bed approved
- ❑ Hospital—Psychiatric Unit
- ❑ Hospital—Rehabilitation Unit
- ❑ Hospital—Specialty Hospital (cardiac, orthopedic, or surgical)
- ❑ Other (Specify):_____

3. Does this hospital have a compliance plan that states that the hospital checks all managing employees against the exclusion/debarment lists of both the HHS Office of the Inspector General (OIG) and the General Services Administration (GSA)?

❑ YES ❑ NO

B. IDENTIFICATION INFORMATION

1. BUSINESS INFORMATION

Legal Business Name (not the "Doing Business As" name) as reported to the Internal Revenue Service

Identify the type of organizational structure of this provider *(Check one)*

❑ Corporation ❑ Limited Liability Company ❑ Partnership ❑ Sole Proprietor ❑ Other (Specify):_____

Tax Identification Number

Incorporation Date *(mm/dd/yyyy) (if applicable)*	State Where Incorporated *(if applicable)*

Other Name

Type of Other Name

❑ Former Legal Business Name ❑ Doing Business As Name ❑ Other (Specify):_____

SECTION 2: IDENTIFYING INFORMATION (Continued)

2. STATE LICENSE INFORMATION/CERTIFICATION INFORMATION

Provide the following information if the provider has a State license/certification to operate as the provider type for which you are enrolling.

❑ State License Not Applicable

License Number	State Where Issued
Effective Date *(mm/dd/yyyy)*	Expiration/Renewal Date *(mm/dd/yyyy)*

Certification Information

❑ Certification Not Applicable

Certification Number	State Where Issued
Effective Date *(mm/dd/yyyy)*	Expiration/Renewal Date *(mm/dd/yyyy)*

C. CORRESPONDENCE ADDRESS

Provide contact information for the entity listed in Section 2B1 of this section. Once enrolled, the information provided below will be used by the fee-for-service contractor if it needs to contact you directly. This address cannot be a billing agency's address.

Mailing Address Line 1 *(Street Name and Number)*

Mailing Address Line 2 *(Suite, Room, etc.)*

City/Town	State	ZIP Code + 4

Telephone Number	Fax Number *(if applicable)*	E-mail Address *(if applicable)*

D. ACCREDITATION

Is this provider accredited? ❑ YES ❑ NO

If YES, complete the following:

Date of Accreditation *(mm/dd/yyyy)*	Name of Accrediting Body

Type of Accreditation or Accreditation Program (e.g., hospital accreditation program, home health accreditation)

E. COMMENTS

Use this section to clarify any information furnished in this section.

SECTION 2: IDENTIFYING INFORMATION (Continued)

F. CHANGE OF OWNERSHIP (CHOW) INFORMATION

Both the seller/former owner and the new owner should complete this section. (As the new owner may not know all of the seller/former owner's data, it should furnish this information on an "if known" basis.) The seller/former owner must complete Sections 1A, 2F, 13, and either 15 or 16. (Section 6 must also be completed if the signer has never completed Section 6 before.) The new owner must complete the entire application.

Legal Business Name of "Seller/Former Owner" as reported to the Internal Revenue Service

"Doing Business As" Name of Seller/Former Owner *(if applicable)*		Old Owner's Medicare Identification Number *(if issued)*
Old Owner's NPI	Effective Date of Transfer *(this can be a future date)(MM/DD/YYYY)*	Name of Fee-For-Service Contractor of Seller/Former Owner

Will the new owner be accepting assignment of the current "Provider Agreement?" ❑ YES ❑ NO

If the answer is "No," then this is an initial enrollment and the new owner should follow the instructions for "New Enrollees" in Section 1 of this form.

Submit one copy of the bill of sale with the application. A copy of the final sales agreement must be submitted once the sale is executed.

G. ACQUISITIONS/MERGERS

Effective Date of Acquisition

The seller/former owner need only complete Sections 1A, 2G, 13, and either 15 or 16; the new owner must complete Sections 1A, 2G, 4, 13, and either 15 or 16. (Section 6 must also be completed if the signer has never completed Section 6 before.)

1. PROVIDER BEING ACQUIRED

This section is to be completed with information about the currently enrolled provider that is being acquired and will no longer retain its current Medicare provider number as a result of this acquisition.

Legal Business Name of the "Provider Being Acquired" as reported to the Internal Revenue Service

Current Fee-for-Service Contractor

Provide the name and Medicare identification number of all units of the above provider that have separate Medicare identification numbers but have not entered into separate provider agreements, such as swing bed units of a hospital and HHA branches. Also furnish the NPI. Units that already have a separate provider agreement should not be reported here.

Name/Department	Medicare Identification Number *(if issued)*	National Provider Identifier
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

SECTION 2: IDENTIFYING INFORMATION (Continued)

2. ACQUIRING PROVIDER

This section is to be completed with information about the organization acquiring the provider identified in Section 2G1.

Legal Business Name of the "Acquiring Provider" as Reported to the Internal Revenue Service	Medicare Identification Number *(if issued)*
Current Fee-for-Service Contractor	National Provider Identifier

Submit one copy of the bill of sale with the application. A copy of the final sales agreement must be submitted once the sale is executed.

H. CONSOLIDATIONS

The newly formed provider completes the entire application. The providers that are being consolidated are reported below.

1. 1ST CONSOLIDATING PROVIDER

This section is to be completed with information about the 1st currently enrolled provider that, as a result of this consolidation, will no longer retain its current Medicare Identification Number.

Legal Business Name of the Provider Organization as Reported to the Internal Revenue Service

Current Fee-for-Service Contractor

Effective Date of Consolidation

Provide the name and Medicare identification number of all units of the above provider that have separate Medicare identification numbers but have not entered into separate provider agreements, such as swing-bed units of a hospital and HHA branches. Also furnish the NPI. Units that already have a separate provider agreement should not be reported here.

Name/Department	Medicare Identification Number *(if issued)*	National Provider Identifier

2. 2ND CONSOLIDATING PROVIDER

This section is to be completed with information about the 2nd currently enrolled provider that, as a result of this consolidation, will also no longer retain its current Medicare Identification Number.

Legal Business Name of the Provider Organization as Reported to the Internal Revenue Service

Current Fee-for-Service Contractor

SECTION 2: IDENTIFYING INFORMATION (Continued)

Provide the name and Medicare identification number of all units of the above provider that have separate Medicare identification numbers but have not entered into separate provider agreements, such as swing-bed units of a hospital and HHA branches. Also furnish the NPI. Units that already have a separate provider agreement should not be reported here.

Name/Department	Medicare Identification Number *(if issued)*	National Provider Identifier

3. NEWLY CREATED PROVIDER IDENTIFICATION INFORMATION

Complete this section with identifying information about the newly created provider resulting from this consolidation.

Legal Business Name of the New Provider as Reported to the Internal Revenue Service	Tax Identification Number

Submit one copy of the bill of sale with the application. A copy of the final sales agreement must be submitted once the sale is executed.

SECTION 3: ADVERSE LEGAL ACTIONS/CONVICTIONS

This section captures information on adverse legal actions, such as convictions, exclusions, revocations, and suspensions. All applicable adverse legal actions must be reported, regardless of whether any records were expunged or any appeals are pending. If you are uncertain as to whether an action falls within one of the adverse legal action categories or whether a name reported on this application has an adverse legal action, query the Healthcare Integrity and Protection Data Bank. For information on how to access the Data Bank, call 1-800-767-6732 or visit *www.npdb-hipdb.com*. There is a charge for using this service.

ADVERSE LEGAL ACTIONS THAT MUST BE REPORTED

Convictions

1. The provider, supplier, or any owner of the provider or supplier was, within the last 10 years preceding enrollment or revalidation of enrollment, convicted of a Federal or State felony offense that CMS has determined to be detrimental to the best interests of the program and its beneficiaries. Offenses include:

   Felony crimes against persons and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pre-trial diversions; financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pre-trial diversions; any felony that placed the Medicare program or its beneficiaries at immediate risk (such as a malpractice suit that results in a conviction of criminal neglect or misconduct); and any felonies that would result in a mandatory exclusion under Section 1128(a) of the Act.

2. Any misdemeanor conviction, under Federal or State law, related to: (a) the delivery of an item or service under Medicare or a State health care program, or (b) the abuse or neglect of a patient in connection with the delivery of a health care item or service.
3. Any misdemeanor conviction, under Federal or State law, related to theft, fraud, embezzlement, breach of fiduciary duty, or other financial misconduct in connection with the delivery of a health care item or service.
4. Any felony or misdemeanor conviction, under Federal or State law, relating to the interference with or obstruction of any investigation into any criminal offense described in 42 C.F.R. Section 1001.101 or 1001.201.
5. Any felony or misdemeanor conviction, under Federal or State law, relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

Exclusions, Revocations or Suspensions

1. Any revocation or suspension of a license to provide health care by any State licensing authority. This includes the surrender of such a license while a formal disciplinary proceeding was pending before a State licensing authority.
2. Any revocation or suspension of accreditation.
3. Any suspension or exclusion from participation in, or any sanction imposed by, a Federal or State health care program, or any debarment from participation in any Federal Executive Branch procurement or non-procurement program.
4. Any current Medicare payment suspension under any Medicare billing number.
5. Any Medicare revocation of any Medicare billing number.

SECTION 3: ADVERSE LEGAL ACTIONS/CONVICTIONS (Continued)

ADVERSE LEGAL HISTORY

1. Has your organization, under any current or former name or business identity, ever had an adverse action listed on page 13 of this application imposed against it?

   ❑ YES–Continue Below ❑ NO–Skip to Section 4

2. If yes, report each adverse legal action, when it occurred, the Federal or State agency or the court/administrative body that imposed the action, and the resolution, if any.

   Attach a copy of the adverse legal action documentation and resolution.

Adverse Legal Action	Date	Taken By	Resolution

SECTION 4: PRACTICE LOCATION INFORMATION

INSTRUCTIONS

- Report all practice locations within the jurisdiction of the Medicare fee-for-service contractor to which you will submit this application.
- If the provider is adding a practice location in the same State and the location requires a separate provider agreement, a separate, complete CMS-855A must be submitted for that location. The location is considered a separate provider for purposes of enrollment, and is not considered a practice location of the main provider. If a provider agreement is not required, the location can be added as a practice location.
- If the provider is adding a practice location in another State and the location requires a separate provider agreement, a separate, complete CMS-855A must be submitted for that location. (This often happens when a home health agency wants to perform services in an adjacent State.)
- If the provider is adding a practice location within another fee-for-service contractor's jurisdiction and the provider is not already enrolled with that fee-for-service contractor, the provider must submit a full, complete CMS-855A to that fee-for-service contractor—regardless of whether a separate provider agreement is required. It cannot add the location as a mere practice location.
- Provide the specific street address as recorded by the United States Postal Service. Do not furnish a P.O. Box.

IMPORTANT: The provider should list its primary practice location first in Section 4A. The "primary practice location" must be associated with the NPI that the provider intends to use to bill for Medicare services.

If you have any questions as to whether the practice location requires a separate State survey or provider agreement, contact your fee-for-service contractor.

Community Mental Health Centers (CMHCs) must report all alternative sites where core services are provided (proposed alternative sites for initial enrollment and actual alternative sites for those CMHCs already participating in Medicare). In accordance with provisions of the Public Health Service Act, a CMHC is required to provide mental health services principally to individuals who reside in a defined geographic area (service area). Therefore, CMHCs must service a distinct and definable community. Those CMHCs operating or proposing to operate outside of this specific community must have a separate provider agreement/number, submit a separate enrollment application, and individually meet the requirements to participate. CMS will determine if the alternative site is permissible or whether the site must have a separate agreement/number. CMS will consider the actual demonstrated transportation pattern of CMHC clients within the community to ensure that all core services and partial hospitalization services are available from each location within the community. A CMHC patient must be able to access and receive services he/she needs at the parent CMHC site or the alternative site within the distinct and definable community served by the parent.

SECTION 4: PRACTICE LOCATION INFORMATION (Continued)

Hospitals must report all practice locations where the hospital provides services. Do not report separately enrolled provider types such as skilled nursing facilities (SNFs), HHAs, RHCs, etc., even if these entities are provider-based to the hospital. Suppose a hospital owns a SNF and an HHA. The hospital should not list the SNF and HHA on its application, as they are not locations where the hospital furnishes services. They are providers that are separate and distinct from the hospital, and will be reported on their respective CMS-855A applications.

Base of Operations Address

- If this provider does not have a physical location where equipment and/or vehicles are stored or from where personnel report on a regular basis, complete this section with information about the location of the dispatcher/scheduler. This situation may occur if the provider operates mobile units that travel continuously from one location directly to another.
- HHAs must complete this section.

Mobile Facility and/or Portable Units

To properly pay claims, Medicare must know when services are provided in a mobile facility or with portable units. (This section is mostly applicable to providers that perform outpatient physical therapy, occupational therapy, and speech pathology services.)

- A “mobile facility” is generally a mobile home, trailer, or other large vehicle that has been converted, equipped, and licensed to render health care services. These vehicles usually travel to local shopping centers or community centers to see and treat patients inside the vehicle.
- A “portable unit” is when the provider transports medical equipment to a fixed location (e.g., a physician’s office or nursing home) to render services to the patient.

SECTION 4: PRACTICE LOCATION INFORMATION (Continued)

A. PRACTICE LOCATION INFORMATION

Report all practice locations where services will be furnished. If there is more than one location, copy and complete this section for each. Please list your primary practice location first.

To ensure that CMS establishes the correct associations between your Medicare legacy number (if issued) and your NPI, you must list a Medicare legacy number—NPI combination for each practice location. If you have multiple NPIs associated with both a single legacy number and a single practice location, please list below all NPIs and associated legacy numbers for that practice location.

If you are changing, adding, or deleting information, check the applicable box, furnish the effective date, and complete the appropriate fields in this section.

CHECK ONE	❑ CHANGE	❑ ADD	❑ DELETE
DATE (mm/dd/yyyy)			

Practice Location Name *("Doing Business As" name if different from Legal Business Name)*

Practice Location Address Line 1 *(Street Name and Number)—(Not a P.O. Box)*

Practice Location Address Line 2 *(Suite, Room, etc.)*

City/Town	State	ZIP Code + 4
Telephone Number	Fax Number *(if applicable)*	E-mail Address *(if applicable)*

Medicare Identification Number *(if issued)*	National Provider Identifier
Medicare Identification Number *(if issued)*	National Provider Identifier
Medicare Identification Number *(if issued)*	National Provider Identifier
Medicare Identification Number *(if issued)*	National Provider Identifier
CLIA Number for this Location *(if applicable)*	FDA/Radiology (Mammography) Certification Number(s) for this location *(if applicable)*

Hospitals and HHAs only (Identify type of practice location):

❑ HHA Branch
❑ Hospital Psychiatric Unit
❑ Hospital Rehabilitation Unit
❑ Hospital Swing-Bed Unit
❑ OPT Extension Site
❑ Other Hospital Practice Location:_____

B. WHERE DO YOU WANT REMITTANCE NOTICES OR SPECIAL PAYMENTS SENT?

If you are changing, adding, or deleting information, check the applicable box, furnish the effective date, and complete the appropriate fields in this section.

CHECK ONE	❑ CHANGE	❑ ADD	❑ DELETE
DATE (mm/dd/yyyy)			

Medicare will issue payments via electronic funds transfer (EFT). Since payment will be made by EFT, the "Special Payments" address will indicate where all other payment information (e.g., remittance notices, special payments) are sent.

SECTION 4: PRACTICE LOCATION INFORMATION (Continued)

❑ "Special Payments" address is the same as the practice location (only one address is listed in Section 4A). **Skip to Section 4C.**

❑ "Special Payments" address is different than that listed in Section 4A, or multiple locations are listed. **Provide address below.**

"Special Payments" Address Line 1 *(PO Box or Street Name and Number)*

"Special Payments" Address Line 2 *(Suite, Room, etc.)*

City/Town	State	ZIP Code + 4

C. WHERE DO YOU KEEP PATIENTS' MEDICAL RECORDS?

If you store patients' medical records (current and/or former patients) at a location other than the location in Section 4A or 4D, complete this section with the address of the storage location.

If this section is not complete, you are indicating that all records are stored at the practice locations reported in Section 4A or 4D. The records must be the provider's records, not the records of another provider. Post Office Boxes and drop boxes are not acceptable as physical addresses where patients' records are maintained. For mobile facilities/portable units, the patients' medical records must be under the provider's control.

If you are changing, adding, or deleting information, check the applicable box, furnish the effective date, and complete the appropriate fields in this section.

First Medical Record Storage Facility for Current and Former Patients

CHECK ONE	❑ CHANGE	❑ ADD	❑ DELETE
DATE (mm/dd/yyyy)			

Storage Facility Address Line 1 *(Street Name and Number)*

Storage Facility Address Line 2 *(Suite, Room, etc.)*

City/Town	State	ZIP Code + 4

SECTION 4: PRACTICE LOCATION INFORMATION (Continued)

Second Medical Record Storage Facility

CHECK ONE	❑ CHANGE	❑ ADD	❑ DELETE
DATE (mm/dd/yyyy)			

Storage Facility Address Line 1 *(Street Name and Number)*

Storage Facility Address Line 2 *(Suite, Room, etc.)*

City/Town	State	ZIP Code + 4

D. BASE OF OPERATIONS ADDRESS FOR MOBILE OR PORTABLE PROVIDERS (LOCATION OF BUSINESS OFFICE OR DISPATCHER/SCHEDULER)

The base of operations is the location from where personnel are dispatched, where mobile/portable equipment is stored, and when applicable, where vehicles are parked when not in use.

If you are changing, adding, or deleting information, check the applicable box, furnish the effective date, and complete the appropriate fields in this section.

CHECK ONE	❑ CHANGE	❑ ADD	❑ DELETE
DATE (mm/dd/yyyy)			

Check here ❑ and skip to Section 4E if the "Base of Operations" address is the same as the "Practice Location" listed in Section 4A.

Street Address Line 1 *(Street Name and Number)*

Street Address Line 2 *(Suite, Room, etc.)*

City/Town		State	ZIP Code + 4
Telephone Number	Fax Number *(if applicable)*	E-mail Address *(if applicable)*	

SECTION 4: PRACTICE LOCATION INFORMATION (Continued)

E. VEHICLE INFORMATION

If the mobile health care services are rendered inside a vehicle, such as a mobile home or trailer, furnish the following vehicle information. Do not furnish information about ambulance vehicles, or vehicles that are used only to transport medical equipment (e.g., when the equipment is transported in a van but is used in a fixed setting, such as a doctor's office). If more than three vehicles are used, copy and complete this section as needed.

If you are changing, adding, or deleting information, check the applicable box, furnish the effective date, and complete the appropriate fields in this section.

CHECK ONE FOR EACH VEHICLE	Type of Vehicle *(van, mobile home, trailer, etc.)*	Vehicle Identification Number
❑ CHANGE ❑ ADD ❑ DELETE		
Effective Date:		
❑ CHANGE ❑ ADD ❑ DELETE		
Effective Date:		
❑ CHANGE ❑ ADD ❑ DELETE		
Effective Date:		

For each vehicle, submit a copy of all health care related permits/licenses/registrations.

F. GEOGRAPHIC LOCATION FOR MOBILE OR PORTABLE PROVIDERS WHERE THE BASE OF OPERATIONS AND/OR VEHICLE RENDERS SERVICES

For home health agencies (HHAs) and mobile/portable providers, furnish information identifying the geographic area(s) where health care services are rendered.

NOTE: If you provide mobile health care services in more than one State and those States are serviced by different Medicare fee-for-service contractors, complete a separate enrollment application (CMS-855A) for each Medicare fee-for-service contractor's jurisdiction.

1. INITIAL REPORTING AND/OR ADDITIONS

If you are reporting or adding an entire State, it is not necessary to report each city/town. Simply check the box below and specify the State.

❑ Entire State of _____

If services are provided in selected cities/towns, provide the locations below. Only list ZIP codes if you are not servicing the entire city/town.

City/Town	State	ZIP Code
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

SECTION 4: PRACTICE LOCATION INFORMATION (Continued)

2. DELETIONS

If you are deleting an entire State, it is not necessary to report each city/town. Simply check the box below and specify the State.

❑ Entire State of _____

If services are provided in selected cities/towns, provide the locations below. Only list ZIP codes if you are not servicing the entire city/town.

City/Town	State	ZIP Code

SECTION 5: OWNERSHIP INTEREST AND/OR MANAGING CONTROL INFORMATION (ORGANIZATIONS)

NOTE: ONLY REPORT ORGANIZATIONS IN THIS SECTION. INDIVIDUALS MUST BE REPORTED IN SECTION 6.

Complete this section with information about all organizations that have 5 percent or more (direct or indirect) ownership interest of, any partnership interest in, and/or managing control of, the provider identified in Section 2, as well as information on any adverse legal actions that have been imposed against that organization. For examples of organizations that should be reported here, visit our Web site: *www.cms.hhs.gov/MedicareProviderSupEnroll*. If there is more than one organization that should be reported, copy and complete this section for each.

MANAGING CONTROL (ORGANIZATIONS)

Any organization that exercises operational or managerial control over the provider, or conducts the day-to-day operations of the provider, is a managing organization and must be reported. The organization need not have an ownership interest in the provider in order to qualify as a managing organization. For instance, it could be a management services organization under contract with the provider to furnish management services for the business.

SPECIAL TYPES OF ORGANIZATIONS

Governmental/Tribal Organizations: If a Federal, State, county, city, or other level of government, or an Indian tribe, will be legally and financially responsible for Medicare payments received (including any potential overpayments), the name of that government or Indian tribe should be reported as an owner. The provider must submit a letter on the letterhead of the responsible government (e.g., government agency) or tribal organization that attests that the government or tribal organization will be legally and financially responsible in the event that there is any outstanding debt owed to CMS. This letter must be signed by an appointed or elected official of the government or tribal organization who has the authority to legally and financially bind the government or tribal organization to the laws, regulations, and program instructions of the Medicare program.

Non-Profit, Charitable and Religious Organizations: Many non-profit organizations are charitable or religious in nature, and are operated and/or managed by a board of trustees or other governing body. The actual name of the board of trustees or other governing body should be reported in this section. While the organization should be listed in Section 5, individual board members should be listed in Section 6. Each non-profit organization should submit a copy of a 501(c)(3) document verifying its non-profit status.

All organizations that have any of the following must be reported in Section 5:

- 5 percent or more ownership (direct or indirect) of the provider,
- Managing control of the provider, or
- A partnership interest in the provider, regardless of the percentage of ownership the partner has.

Owning/Managing organizations are generally one of the following types:

- Corporations (including non-profit corporations)
- Partnerships and Limited Partnerships (as indicated above)
- Limited Liability Companies
- Charitable and/or Religious organizations
- Governmental and/or Tribal organizations

SECTION 5: OWNERSHIP INTEREST AND/OR MANAGING CONTROL INFORMATION (ORGANIZATIONS) (Continued)

A. ORGANIZATION WITH OWNERSHIP INTEREST AND/OR MANAGING CONTROL—IDENTIFICATION INFORMATION

❑ Not Applicable

If you are changing, adding, or deleting information, check the applicable box, furnish the effective date, and complete the appropriate fields in this section.

CHECK ONE	❑ CHANGE	❑ ADD	❑ DELETE
DATE (mm/dd/yyyy)			

Check all that apply:

❑ 5 Percent or More Ownership Interest ❑ Partner ❑ Managing Control

Legal Business Name as reported to the Internal Revenue Service

"Doing Business As" Name *(if applicable)*

Address Line 1 *(Street Name and Number)*

Address Line 2 *(Suite, Room, etc.)*

City/Town	State	ZIP Code + 4

Tax Identification Number *(Required)*

Medicare Identification Number(s) *(if issued)*	NPI *(if issued)*

SECTION 5: OWNERSHIP INTEREST AND/OR MANAGING CONTROL INFORMATION (ORGANIZATIONS) (Continued)

B. ADVERSE LEGAL HISTORY

If reporting a change to existing information, check "Change," provide the effective date of the change, and complete the appropriate fields in this section.

❑ Change ❑ Effective Date:_____

1. Has this organization in Section 5A, under any current or former name or business identity, ever had an adverse legal action listed on page 13 of this application imposed against it?

❑ YES – Continue Below	❑ NO – Skip to Section 6

2. If YES, report each adverse legal action, when it occurred, the Federal or State agency or the court/administrative body that imposed the action, and the resolution.

   Attach a copy of the adverse legal action documentation(s) and resolution(s).

Adverse Legal Action	Date	Taken By	Resolution

SECTION 6: OWNERSHIP INTEREST AND/OR MANAGING CONTROL INFORMATION (INDIVIDUALS)

NOTE: Only Individuals should be reported in Section 6. Organizations must be reported in Section 5. For more information on "direct" and "indirect" owners, go to *www.cms.hhs.gov/MedicareProviderSupEnroll*.

The provider MUST have at least ONE owner and/or managing employee. If there is more than one person listed in this section, copy and complete this section for each.

The following individuals must be reported in Section 6A:

- All persons who have a 5 percent or greater direct or indirect ownership interest in the provider;
- If (and only if) the provider is a corporation (whether for-profit or non-profit), all officers and directors of the provider;
- All managing employees of the provider;
- All individuals with a partnership interest in the provider, regardless of the percentage of ownership the partner has; and
- Authorized and delegated officials.

Example: A provider is 100 percent owned by Company C, which itself is 100 percent owned by Individual D. Assume that Company C is reported in Section 5A as an owner of the provider. Assume further that Individual D, as an indirect owner of the provider, is reported in Section 6A1. Based on this example, the provider would check the "5 Percent or Greater Direct/Indirect Owner" box in Section 6A2.

NOTE: All partners within a partnership must be reported on this application. This applies to both "General" and "Limited" partnerships. For instance, if a limited partnership has several limited partners and each of them only has a 1 percent interest in the provider, each limited partner must be reported on this application, even though each owns less than 5 percent. The 5 percent threshold primarily applies to corporations and other organizations that are not partnerships.

Non-Profit, Charitable or Religious Organizations: If you are a non-profit charitable or religious organization that has no organizational or individual owners (only board members, directors or managers), you should submit with your application a 501(c)(3) document verifying non-profit status.

SECTION 6: OWNERSHIP INTEREST AND/OR MANAGING CONTROL INFORMATION (INDIVIDUALS) (Continued)

For purposes of this application, the terms "officer," "director," and "managing employee" are defined as follows:

Officer is any person whose position is listed as being that of an officer in the provider's "articles of incorporation" or "corporate bylaws," or anyone who is appointed by the board of directors as an officer in accordance with the provider's corporate bylaws.

Director is a member of the provider's "board of directors." It does not necessarily include a person who may have the word "director" in his/her job title (e.g., departmental director, director of operations). Moreover, where a provider has a governing body that does not use the term "board of directors," the members of that governing body will still be considered "directors." Thus, if the provider has a governing body titled "board of trustees" (as opposed to "board of directors"), the individual trustees are considered "directors" for Medicare enrollment purposes.

Managing Employee means a general manager, business manager, administrator, director, or other individual who exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operations of the provider, either under contract or through some other arrangement, regardless of whether the individual is a W-2 employee of the provider.

NOTE: If a governmental or tribal organization will be legally and financially responsible for Medicare payments received (per the instructions for Governmental/Tribal Organizations in Section 5), the provider is only required to report its managing employees in Section 6. Owners, partners, officers, and directors do not need to be reported, except those who are listed as authorized or delegated officials on this application.

SECTION 6: OWNERSHIP INTEREST AND/OR MANAGING CONTROL INFORMATION (INDIVIDUALS) (Continued)

Any information on adverse legal actions that have been imposed against the individuals reported in this section must be furnished. If there is more than one individual, copy and complete this section for each individual in Section 6B.

A. INDIVIDUALS WITH OWNERSHIP INTEREST AND/OR MANAGING CONTROL—IDENTIFICATION INFORMATION

If you are changing, adding, or deleting information, check the applicable box, furnish the effective date, and complete the appropriate fields in this section. The name, date of birth, and social security number of each person listed in this section must coincide with the individual's information as listed with the Social Security Administration.

CHECK ONE	❑ CHANGE	❑ ADD	❑ DELETE
DATE (mm/dd/yyyy)			

1. First Name	Middle Initial	Last Name	Jr., Sr., etc.
Social Security Number *(Required)*	Date of Birth *(mm/dd/yyyy)*	Medicare Identification Number *(if issued)*	NPI *(if issued)*

2. What is the above individual's relationship with the provider in Section 2B1? *(Check all that apply.)*

❑ 5 Percent or Greater Direct/Indirect Owner
❑ Partner
❑ Managing Employee (W-2)
❑ Director/Officer
❑ Contracted Managing Employee
❑ Other _____

B. ADVERSE LEGAL HISTORY

Complete this section for the individual reported in Section 6A above.

If you are changing information, check "change" box, furnish the effective date, and complete the appropriate fields in this section.

❑ Change ❑ Effective Date:_____

1. Has the individual in Section 6A, under any current or former name or business identity, ever had an adverse legal action listed on page 13 of this application imposed against him/her?

❑ YES–Continue Below ❑ NO–Skip to Section 7

2. If YES, report each adverse legal action, when it occurred, the Federal or State agency or the court/administrative body that imposed the action, and the resolution, if any.

Attach a copy of the adverse legal action documentation and resolution.

Adverse Legal Action	Date	Taken By	Resolution

SECTION 7: CHAIN HOME OFFICE INFORMATION

This section captures information regarding chain organizations. This information will be used to ensure proper reimbursement when the provider's year-end cost report is filed with the Medicare fee-for-service contractor.

For more information on chain organizations, see 42 C.F.R. 421.404.

CHECK HERE ❑ IF THIS SECTION DOES NOT APPLY AND SKIP TO SECTION 8.

A. TYPE OF ACTION THIS PROVIDER IS REPORTING

Check one:	Effective Date	**Sections to Complete**
❑ Provider in chain is enrolling in Medicare for the first time *(Initial Enrollment or Change of Ownership)*.	_____	Complete all of Section 7.
❑ Provider is no longer associated with the chain organization previously reported.	_____	Complete Section 7C, identifying the former chain home office.
❑ Provider has changed from one chain to another.	_____	Complete Section 7 in full to identify the new chain home office.
❑ The name of provider's chain home office is changing *(all other information remains the same)*.	_____	Complete Section 7C.

B. CHAIN HOME OFFICE ADMINISTRATOR INFORMATION

Name of Home Office Administrator or CEO — First Name	Middle Initial	Last Name	Jr., Sr., etc.

Title of Home Office Administrator	Social Security Number	Date of Birth *(mm/dd/yyyy)*

SECTION 7: CHAIN HOME OFFICE INFORMATION (Continued)

C. CHAIN HOME OFFICE INFORMATION

1. Name of Home Office as Reported to the Internal Revenue Service

2. Home Office Business Street Address Line 1 *(Street Name and Number)*

Home Office Business Street Address Line 2 *(Suite, Room, etc.)*

City/Town	State	ZIP Code + 4

Telephone Number	Fax Number *(if applicable)*	E-mail Address *(if applicable)*

3. Home Office Tax Identification Number	Home Office Cost Report Year-End Date *(mm/dd)*
4. Home Office Fee-For-Service Contractor	Home Office Chain Number

D. TYPE OF BUSINESS STRUCTURE OF THE CHAIN HOME OFFICE

Check one:

Voluntary:
- ❑ Non-Profit – Religious Organization
- ❑ Non-Profit – Other *(Specify)*: _____

Proprietary:
- ❑ Individual
- ❑ Corporation
- ❑ Partnership _____
- ❑ Other *(Specify)*: _____

Government:
- ❑ Federal
- ❑ State
- ❑ City
- ❑ County
- ❑ City-County
- ❑ Hospital District
- ❑ Other *(Specify)*: _____

E. PROVIDER'S AFFILIATION TO THE CHAIN HOME OFFICE

Check one:

- ❑ Joint Venture/Partnership
- ❑ Operated/Related
- ❑ Managed/Related
- ❑ Wholly Owned
- ❑ Leased
- ❑ Other *(Specify)*: _____

SECTION 8: BILLING AGENCY INFORMATION

Applicants that use a billing agency must complete this section. A billing agency is a company or individual that you contract with to process and submit your claims. If you use a billing agency, you are responsible for the claims submitted on your behalf.

❑ **Check here if this section does not apply and skip to Section 12.**

BILLING AGENCY NAME AND ADDRESS

If you are changing, adding, or deleting information, check the applicable box, furnish the effective date, and complete the appropriate fields in this section.

CHECK ONE	❑ CHANGE	❑ ADD	❑ DELETE
DATE (mm/dd/yyyy)			

Legal Business/Individual Name as Reported to the Social Security Administration or Internal Revenue Service

Tax Identification Number or Social Security Number *(required)*

"Doing Business As" Name *(if applicable)*

Billing Agency Address Line 1 *(Street Name and Number)*

Billing Agency Address Line 2 *(Suite, Room, etc.)*

City/Town	State	ZIP Code + 4

Telephone Number	Fax Number *(if applicable)*	E-mail Address *(if applicable)*

SECTION 9: FOR FUTURE USE (This Section Not Applicable)

SECTION 10: FOR FUTURE USE (This Section Not Applicable)

SECTION 11: FOR FUTURE USE (This Section Not Applicable)

SECTION 12: SPECIAL REQUIREMENTS FOR HOME HEALTH AGENCIES (HHAs)

INSTRUCTIONS

All HHAs and HHA sub-units enrolling in the Medicare program must complete this section. HHAs and HHA sub-units initially enrolling in Medicare, Medicaid, or both programs on or after January 1, 1998 are required to provide documentation supporting that they have sufficient initial reserve operating funds (capitalization) to operate for the first three months in the Medicare and/or Medicaid program(s). The capitalization requirement applies to all HHAs and HHA sub-units enrolling in the Medicare program, including HHAs or HHA sub-units currently participating in the Medicare program that, as a result of a change of ownership, will be issued a new provider number. The capitalization requirement does not apply to a branch of an HHA. Regulations found at 42 C.F.R. 489.28 require that the fee-for-service contractor determine the required amount of reserve operating funds needed for the enrolling HHA or HHA sub-unit by comparing the enrolling HHA or HHA sub-unit to at least three other new HHAs that it serves which are comparable to the enrolling HHA or HHA sub-unit. Factors to be considered are geographic location, number of visits, type of HHA or HHA sub-unit and business structure of the HHA or HHA sub-unit. The fee-for-service contractor then verifies that the enrolling HHA or HHA sub-unit has the required funds. To assist the fee-for-service contractor in determining the amount of funds necessary, the enrolling HHA or HHA sub-unit should complete this section.

CHECK HERE ❑ IF THIS SECTION DOES NOT APPLY AND SKIP TO SECTION 13.

A. TYPE OF HOME HEALTH AGENCY

1. CHECK ONE:

❑ Non-Profit Agency ❑ Proprietary Agency

2. PROJECTED NUMBER OF VISITS BY THIS HOME HEALTH AGENCY

How many visits does this HHA project it will make in the first: three months of operation?_____
twelve months of operation? _____

3. FINANCIAL DOCUMENTATION

A) In order to expedite the enrollment process, the HHA may attach a copy of its most current savings, checking, or other financial statement(s) that verifies the initial reserve operating funds, accompanied by:

1) An attestation from an officer of the bank or other financial institution stating that the funds are in the account(s) and are immediately available for the HHA's use, and
2) Certification from the HHA attesting that at least 50% of the reserve operating funds are non-borrowed funds.

B) Will the HHA be submitting the above documentation with this application? ❑ YES ❑ NO

NOTE: The fee-for-service contractor may require a subsequent attestation that the funds are still available. If the fee-for-service contractor determines that the HHA requires funds in addition to those indicated on the originally submitted account statement(s), it will require verification of the additional amount as well as a new attestation statement.

SECTION 12: SPECIAL REQUIREMENTS FOR HOME HEALTH AGENCIES (HHAs) (Continued)

4. ADDITIONAL INFORMATION

Provide any additional documentation necessary to assist the fee-for-service contractor or State agency in properly comparing this HHA with other comparable HHAs. Use this space to explain or justify any unique financial situations of this HHA that may be helpful in determining the HHA's compliance with the capitalization requirements.

B. NURSING REGISTRIES

If you are changing, adding, or deleting information, check the applicable box, furnish the effective date, and complete the appropriate fields in this section.

CHECK ONE	❑ CHANGE	❑ ADD	❑ DELETE
DATE (mm/dd/yyyy)			

Does this HHA contract with a nursing registry whereby the latter furnishes personnel to perform HHA services on behalf of the provider?

❑ YES–Furnish the information below
❑ NO–Skip to Section 13

Legal Business Name as Reported to the Internal Revenue Service

Tax Identification Number *(required)*:

"Doing Business As" Name *(if applicable)*

Business Street Address Line 1 *(Street Name and Number)*

Business Street Address Line 2 *(Suite, Room, etc.)*

City/Town	State	ZIP Code + 4

Telephone Number	Fax Number *(if applicable)*	E-mail Address *(if applicable)*

SECTION 13: CONTACT PERSON

If questions arise during the processing of this application, the fee-for-service contractor will contact the individual shown below. If the contact person is an authorized or delegated official, check the appropriate box below and skip to the section indicated.

❑ Contact an Authorized Official listed in Section 15
❑ Contact a Delegated Official listed in Section 16

First Name	Middle Initial	Last Name
Telephone Number		Fax Number *(if applicable)*

Address Line 1 *(Street Name and Number)*

Address Line 2 *(Suite, Room, etc.)*

City/Town	State	ZIP Code + 4

E-mail Address

SECTION 14: PENALTIES FOR FALSIFYING INFORMATION

This section explains the penalties for deliberately furnishing false information in this application to gain or maintain enrollment in the Medicare program.

1. 1. 18 U.S.C. § 1001 authorizes criminal penalties against an individual who, in any matter within the jurisdiction of any department or agency of the United States, knowingly and willfully falsifies, conceals or covers up by any trick, scheme or device a material fact, or makes any false, fictitious, or fraudulent statements or representations, or makes any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry. Individual offenders are subject to fines of up to $250,000 and imprisonment for up to five years. Offenders that are organizations are subject to fines of up to $500,000 (18 U.S.C. § 3571). Section 3571(d) also authorizes fines of up to twice the gross gain derived by the offender if it is greater than the amount specifically authorized by the sentencing statute.
2. Section 1128B(a)(1) of the Social Security Act authorizes criminal penalties against any individual who, "knowingly and willfully," makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under a Federal health care program. The offender is subject to fines of up to $25,000 and/or imprisonment for up to five years.
3. The Civil False Claims Act, 31 U.S.C. § 3729, imposes civil liability, in part, on any person who:
   a) knowingly presents, or causes to be presented, to an officer or any employee of the United States Government a false or fraudulent claim for payment or approval;
   b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; or
   c) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

   The Act imposes a civil penalty of $5,000 to $10,000 per violation, plus three times the amount of damages sustained by the Government
4. Section 1128A(a)(1) of the Social Security Act imposes civil liability, in part, on any person (including an organization, agency or other entity) that knowingly presents or causes to be presented to an officer, employee, or agent of the United States, or of any department or agency thereof, or of any State agency…a claim…that the Secretary determines is for a medical or other item or service that the person knows or should know:
   a) was not provided as claimed; and/or
   b) the claim is false or fraudulent.

   This provision authorizes a civil monetary penalty of up to $10,000 for each item or service, an assessment of up to three times the amount claimed, and exclusion from participation in the Medicare program and State health care programs.
5. 18 U.S.C. 1035 authorizes criminal penalties against individuals in any matter involving a health care benefit program who knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact; or makes any materially false, fictitious, or fraudulent statements or representations, or makes or uses any materially false fictitious, or fraudulent statement or entry, in connection with the delivery of or payment for health care benefits, items or services. The individual shall be fined or imprisoned up to 5 years or both.

SECTION 14: PENALTIES FOR FALSIFYING INFORMATION (Continued)

6. 18 U.S.C. 1347 authorizes criminal penalties against individuals who knowing and willfully execute, or attempt, to executive a scheme or artifice to defraud any health care benefit program, or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by or under the control of any, health care benefit program in connection with the delivery of or payment for health care benefits, items, or services. Individuals shall be fined or imprisoned up to 10 years or both. If the violation results in serious bodily injury, an individual will be fined or imprisoned up to 20 years, or both. If the violation results in death, the individual shall be fined or imprisoned for any term of years or for life, or both.
7. The government may assert common law claims such as "common law fraud," "money paid by mistake," and "unjust enrichment."

   Remedies include compensatory and punitive damages, restitution, and recovery of the amount of the unjust profit.

SECTION 15: CERTIFICATION STATEMENT

An **AUTHORIZED OFFICIAL** means an appointed official (for example, chief executive officer, chief financial officer, general partner, chairman of the board, or direct owner) to whom the organization has granted the legal authority to enroll it in the Medicare program, to make changes or updates to the organization's status in the Medicare program, and to commit the organization to fully abide by the statutes, regulations, and program instructions of the Medicare program.

A **DELEGATED OFFICIAL** means an individual who is delegated by an authorized official the authority to report changes and updates to the provider's enrollment record. A delegated official must be an individual with an "ownership or control interest in" (as that term is defined in Section 1124(a)(3) of the Social Security Act), or be a W-2 managing employee of, the provider.

Delegated officials may not delegate their authority to any other individual. Only an authorized official may delegate the authority to make changes and/or updates to the provider's Medicare status. Even when delegated officials are reported in this application, an authorized official retains the authority to make any such changes and/or updates by providing his or her printed name, signature, and date of signature as required in Section 15B.

NOTE: Authorized officials and delegated officials must be reported in Section 6, either on this application or on a previous application to this same Medicare fee-for-service contractor. **If this is the first time an authorized and/or delegated official has been reported on the CMS-855A, you must complete Section 6 for that individual.**

By his/her signature(s), an authorized official binds the provider to all of the requirements listed in the Certification Statement and acknowledges that the provider may be denied entry to or revoked from the Medicare program if any requirements are not met. All signatures must be original and in ink. Faxed, photocopied, or stamped signatures will not be accepted.

Only an authorized official has the authority to sign (1) the initial enrollment application on behalf of the provider or (2) the enrollment application that must be submitted as part of the periodic revalidation process. A delegated official does not have this authority.

By signing this application, an authorized official agrees to immediately notify the Medicare fee-for-service contractor if any information furnished on this application is not true, correct, or complete. In addition, an authorized official, by his/her signature, agrees to notify the Medicare fee-for-service contractor of any future changes to the information contained in this form, after the provider is enrolled in Medicare, in accordance with the timeframes established in 42 C.F.R. 424.520 (b).

The provider can have as many authorized officials as it wants. If the provider has more than two authorized officials, it should copy and complete this section as needed.

Each authorized and delegated official must have and disclose his/her social security number.

SECTION 15: CERTIFICATION STATEMENT (Continued)

A. ADDITIONAL REQUIREMENTS FOR MEDICARE ENROLLMENT

These are additional requirements that the provider must meet and maintain in order to bill the Medicare program. Read these requirements carefully. By signing, the provider is attesting to having read the requirements and understanding them.

By his/her signature(s), the authorized official(s) named below and the delegated official(s) named in Section 16 agree to adhere to the following requirements stated in this Certification Statement:

1. I agree to notify the Medicare contractor of any future changes to the information contained in this application in accordance with the time frames established in 42 C.F.R. § 424.520(b). I understand that any change in the business structure of this provider may require the submission of a new application.

2. I have read and understand the Penalties for Falsifying Information, as printed in this application. I understand that any deliberate omission, misrepresentation, or falsification of any information contained in this application or contained in any communication supplying information to Medicare, or any deliberate alteration of any text on this application form, may be punished by criminal, civil, or administrative penalties including, but not limited to, the denial or revocation of Medicare billing privileges, and/or the imposition of fines, civil damages, and/or imprisonment.

3. I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare.

4. Neither this provider, nor any five percent or greater owner, partner, officer, director, managing employee, authorized official, or delegated official thereof is currently sanctioned, suspended, debarred, or excluded by the Medicare or State Health Care Program, e.g., Medicaid program, or any other Federal program, or is otherwise prohibited from supplying services to Medicare or other Federal program beneficiaries.

5. I agree that any existing or future overpayment made to the provider by the Medicare program may be recouped by Medicare through the withholding of future payments.

6. I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

7. I authorize any national accrediting body whose standards are recognized by the Secretary as meeting the Medicare program participation requirements, to release to any authorized representative, employee, or agent of the Centers for Medicare & Medicaid Services (CMS), a copy of my most recent accreditation survey, together with any information related to the survey that CMS may require (including corrective action plans).

SECTION 15: CERTIFICATION STATEMENT (Continued)

B. 1ST AUTHORIZED OFFICIAL SIGNATURE

I have read the contents of this application. My signature legally and financially binds this provider to the laws, regulations, and program instructions of the Medicare program. By my signature, I certify that the information contained herein is true, correct, and complete, and I authorize the Medicare fee-for-service contractor to verify this information. If I become aware that any information in this application is not true, correct, or complete, I agree to notify the Medicare fee-for-service contractor of this fact immediately.

If you are changing, adding, or deleting information, check the applicable box, furnish the effective date, and complete the appropriate fields in this section.

CHECK ONE	❑ CHANGE	❑ ADD	❑ DELETE
DATE (mm/dd/yyyy)			

Authorized Official's Information and Signature

First Name	Middle Initial	Last Name	Suffix *(e.g., Jr., Sr.)*

Telephone Number	Title/Position
Authorized Official Signature *(First, Middle, Last Name, Jr., Sr., M.D., D.O., etc.)*	Date Signed *(mm/dd/yyyy)*

C. 2ND AUTHORIZED OFFICIAL SIGNATURE

I have read the contents of this application. My signature legally and financially binds this provider to the laws, regulations, and program instructions of the Medicare program. By my signature, I certify that the information contained herein is true, correct, and complete, and I authorize the Medicare fee-for-service contractor to verify this information. If I become aware that any information in this application is not true, correct, or complete, I agree to notify the Medicare fee-for-service contractor of this fact immediately.

If you are changing, adding, or deleting information, check the applicable box, furnish the effective date, and complete the appropriate fields in this section.

CHECK ONE	❑ CHANGE	❑ ADD	❑ DELETE
DATE (mm/dd/yyyy)			

Authorized Official's Information and Signature

First Name	Middle Initial	Last Name	Suffix *(e.g., Jr., Sr.)*

Telephone Number	Title/Position
Authorized Official Signature *(First, Middle, Last Name, Jr., Sr., M.D., D.O., etc.)*	Date Signed *(mm/dd/yyyy)*

All signatures must be original and signed in ink. Applications with signatures deemed not original will not be processed. Stamped, faxed or copied signatures will not be accepted.

SECTION 16: DELEGATED OFFICIAL(S) (OPTIONAL)

- You are not required to have a delegated official. However, if no delegated official is assigned, the authorized official(s) will be the only person(s) who can make changes and/or updates to the provider's status in the Medicare program.
- The signature of a delegated official shall have the same force and effect as that of an authorized official, and shall legally and financially bind the provider to the laws, regulations, and program instructions of the Medicare program. By his or her signature, the delegated official certifies that he or she has read the Certification Statement in Section 15 and agrees to adhere to all of the stated requirements. The delegated official also certifies that he/she meets the definition of a delegated official. When making changes and/or updates to the provider's enrollment information maintained by the Medicare program, the delegated official certifies that the information provided is true, correct, and complete.
- Delegated officials being deleted do not have to sign or date this application.
- Independent contractors are not considered "employed" by the provider and, therefore, cannot be delegated officials.
- The signature(s) of an authorized official in Section 16 constitutes a legal delegation of authority to any and all delegated official(s) assigned in Section 16.
- If there are more than two individuals, copy and complete this section for each individual.

A. 1ST DELEGATED OFFICIAL SIGNATURE

If you are changing, adding, or deleting information, check the applicable box, furnish the effective date, and complete the appropriate fields in this section.

CHECK ONE	❑ CHANGE	❑ ADD	❑ DELETE
DATE (mm/dd/yyyy)			

Delegated Official First Name	Middle Initial	Last Name	Suffix *(e.g., Jr., Sr.)*

Delegated Official Signature *(First, Middle, Last Name, Jr., Sr., M.D., D.O., etc.)*	Date Signed *(mm/dd/yyyy)*

❑ Check here if Delegated Official is a W-2 Employee	Telephone Number

Authorized Official Signature Assigning this Delegation *(First, Middle, Last Name, Jr., Sr., M.D., D.O., etc.)*	Date Signed *(mm/dd/yyyy)*

SECTION 16: DELEGATED OFFICIAL(S) (OPTIONAL) (Continued)

B. 2ND DELEGATED OFFICIAL SIGNATURE

If you are changing, adding, or deleting information, check the applicable box, furnish the effective date, and complete the appropriate fields in this section.

CHECK ONE	❑ CHANGE	❑ ADD	❑ DELETE
DATE (mm/dd/yyyy)			

Delegated Official First Name	Middle Initial	Last Name	Suffix *(e.g., Jr., Sr.)*

Delegated Official Signature *(First, Middle, Last Name, Jr., Sr., M.D., D.O., etc.)*	Date Signed *(mm/dd/yyyy)*

❑ Check here if Delegated Official is a W-2 Employee	Telephone Number

Authorized Official Assigning this Delegation *(First, Middle, Last Name, Jr., Sr., M.D., D.O., etc.)*	Date Signed *(mm/dd/yyyy)*
Signature	

SECTION 17: SUPPORTING DOCUMENTS

This section lists the documents that, if applicable, must be submitted with this completed enrollment application. If you are newly enrolling, or are reactivating or revalidating your enrollment, you must provide all applicable documents. For changes, only submit documents that are applicable to that change. The enrolling provider may submit a notarized copy of a Certificate of Good Standing from the provider's State licensing/certification board or other medical associations in lieu of copies of the above-requested documents. This certification cannot be more than 30 days old.

The fee-for-service contractor may request, at any time during the enrollment process, documentation to support or validate information that you have reported in this application.

MANDATORY FOR ALL PROVIDER/SUPPLIER TYPES

Required documents that can only be obtained after a State survey are not required as part of the application submission but must be furnished within 30 days of the provider receiving them. The Medicare fee-for-service contractor will furnish specific licensing requirements for your provider type upon request.

- ❏ Licenses, certifications and registrations required by Medicare or State law.
- ❏ Federal, State, and/or local (city/county) business licenses, certifications and/or registrations required to operate a health care facility.
- ❏ Written confirmation from the IRS confirming your Tax Identification Number with the Legal Business Name (e.g., IRS CP 575) provided in Section 2.
- ❏ Completed Form CMS-588, Authorization Agreement for Electronic Funds Transfer. Note: If a provider already receives payments electronically and is not making a change to its banking information, the CMS-588 is not required.

MANDATORY FOR SELECTED PROVIDER/SUPPLIER TYPES

- ❏ Copy(s) of all bills of sale or sales agreements (CHOWS, Acquisition/Mergers, and Consolidations only).
- ❏ Copy(s) of all documents that demonstrate meeting capitalization requirements (HHAs only).

MANDATORY, IF APPLICABLE

- ❏ Statement in writing from the bank. If Medicare payment due a provider of services is being sent to a bank (or similar financial institution) with whom the provider has a lending relationship (that is, any type of loan), then the provider must provide a statement in writing from the bank (which must be in the loan agreement) that the bank has agreed to waive its right of offset for Medicare receivables.
- ❏ Copy(s) of all adverse legal action documentation (e.g., notifications, resolutions, and reinstatement letters).
- ❏ Copy of an attestation for government entities and tribal organizations
- ❏ Copy of HRSA Notice of Grant Award if that is a qualifying document for FQHC status

MEDICARE SUPPLIER ENROLLMENT APPLICATION
PRIVACY ACT STATEMENT

The Centers for Medicare and Medicaid Services (CMS) is authorized to collect the information requested on this form by Sections 1124(a)(1), 1124A(a)(3), 1128, 1814, 1815, 1833(e), and 1842(r) of the Social Security Act [42 U.S.C. §§ 1320a-3(a)(1), 1320a-7, 1395f, 1395g, 1395(l)(e), and 1395u(r)] and Section 31001(1) of the Debt Collection Improvement Act [31 U.S.C. § 7701(c)].

The purpose of collecting this information is to determine or verify the eligibility of individuals and organizations to enroll in the Medicare program as suppliers of goods and services to Medicare beneficiaries and to assist in the administration of the Medicare program. This information will also be used to ensure that no payments will be made to providers who are excluded from participation in the Medicare program. All information on this form is required, with the exception of those sections marked as "optional" on the form. Without this information, the ability to make payments will be delayed or denied.

The information collected will be entered into the Provider Enrollment, Chain and Ownership System (PECOS). The information in this application will be disclosed according to the routine uses described below.

Information from these systems may be disclosed under specific circumstances to:

1. CMS contractors to carry out Medicare functions, collating or analyzing data, or to detect fraud or abuse;
2. A congressional office from the record of an individual health care provider in response to an inquiry from the congressional office at the written request of that individual health care practitioner;
3. The Railroad Retirement Board to administer provisions of the Railroad Retirement or Social Security Acts;
4. Peer Review Organizations in connection with the review of claims, or in connection with studies or other review activities, conducted pursuant to Part B of Title XVIII of the Social Security Act;
5. To the Department of Justice or an adjudicative body when the agency, an agency employee, or the United States Government is a party to litigation and the use of the information is compatible with the purpose for which the agency collected the information;
6. To the Department of Justice for investigating and prosecuting violations of the Social Security Act, to which criminal penalties are attached;
7. To the American Medical Association (AMA), for the purpose of attempting to identify medical doctors when the Unique Physician Identification Number Registry is unable to establish identity after matching contractor submitted data to the data extract provided by the AMA;
8. An individual or organization for a research, evaluation, or epidemiological project related to the prevention of disease or disability, or to the restoration or maintenance of health;
9. Other Federal agencies that administer a Federal health care benefit program to enumerate/enroll providers of medical services or to detect fraud or abuse;
10. State Licensing Boards for review of unethical practices or non-professional conduct;
11. States for the purpose of administration of health care programs; and/or
12. Insurance companies, self insurers, health maintenance organizations, multiple employer trusts, and other health care groups providing health care claims processing, when a link to Medicare or Medicaid claims is established, and data are used solely to process supplier's health care claims.

The enrolling supplier should be aware that the Computer Matching and Privacy Protection Act of 1988 (P.L. 100-503) amended the Privacy Act, 5 U.S.C. § 552a, to permit the government to verify information through computer matching.

Protection of Proprietary Information

Privileged or confidential commercial or financial information collected in this form is protected from public disclosure by Federal law 5 U.S.C. § 552(b)(4) and Executive Order 12600.

Protection of Confidential Commercial and/or Sensitive Personal Information

If any information within this application (or attachments thereto) constitutes a trade secret or privileged or confidential information (as such terms are interpreted under the Freedom of Information Act and applicable case law), or is of a highly sensitive personal nature such that disclosure would constitute a clearly unwarranted invasion of the personal privacy of one or more persons, then such information will be protected from release by CMS under 5 U.S.C. §§ 552(b)(4) and/or (b)(6), respectively.

EXHIBIT J

MEDICARE ENROLLMENT APPLICATION

PHYSICIANS AND NON-PHYSICIAN PRACTITIONERS

CMS-855I

SEE PAGE 1 TO DETERMINE IF YOU ARE COMPLETING THE CORRECT APPLICATION.

SEE PAGE 2 FOR INFORMATION ON WHERE TO MAIL THIS APPLICATION.

SEE PAGE 27 TO FIND THE LIST OF THE SUPPORTING DOCUMENTATION THAT MUST BE SUBMITTED WITH THIS APPLICATION.

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB NO. 0938-0685

WHO SHOULD COMPLETE THIS APPLICATION

All physicians, as well as all non-physician practitioners listed below, must complete this application to initiate the enrollment process:

Anesthesiology Assistant
Audiologist
Certified nurse midwife
Certified registered nurse anesthetist
Clinical nurse specialist
Clinical social worker
Mass immunization roster biller
Nurse practitioner
Occupational therapist in private practice
Physical therapist in private practice
Physician assistant
Psychologist, Clinical
Psychologist billing independently
Registered Dietitian or Nutrition Professional
Speech Language Pathologist

If your supplier type is not listed above, contact your designated fee-for-service contractor before you submit this application.

Complete this application if you are an individual practitioner who plans to bill Medicare and you are:

- An individual practitioner who will provide services in a private setting.
- An individual practitioner who will provide services in a group setting. If you plan to render all of your services in a group setting, you will complete Sections 1-4 and skip to Sections 14 through 17 of this application.
- Currently enrolled with a Medicare fee-for-service contractor but need to enroll in another fee-for-service contractor's jurisdiction (e.g., you have opened a practice location in a geographic territory serviced by another Medicare fee-for-service contractor).
- Currently enrolled in Medicare and need to make changes to your enrollment information (e.g., you have added or changed a practice location).
- An individual who has formed a professional corporation, professional association, limited liability company, etc., of which you are the sole owner.

If you provide services in a group/organization setting, you will also need to complete a separate application, the CMS-855R, to reassign your benefits to each organization. If you terminate your association with an organization, use the CMS-855R to submit that change.

BILLING NUMBER INFORMATION

The NPI is the standard unique health identifier for health care providers and is assigned by the National Plan and Provider Enumeration System (NPPES). **As a Medicare healthcare supplier, you must obtain an NPI prior to enrolling in Medicare or before submitting a change to your existing Medicare enrollment information.** Applying for the NPI is a process separate from Medicare enrollment. To obtain an NPI, you may apply online at *https://NPPES.cms.hhs.gov*. For more information about NPI enumeration, visit *www.cms.hhs.gov/NationalProvIdentStand*.

The Medicare Identification Number, often referred to as a Provider Transaction Access Number (PTAN) or Medicare Legacy Number, is a generic term for any number other than the NPI that is used to identify a Medicare supplier.

INSTRUCTIONS FOR COMPLETING AND SUBMITTING THIS APPLICATION

- Type or print all information so that it is legible. Do not use pencil.
- Report additional information within a section by copying and completing that section for each additional entry.
- Attach all required supporting documentation.
- Keep a copy of your completed Medicare enrollment package for your own records.
- Send the completed application with original signatures and all required documentation to your designated fee-for-service contractor.

AVOID DELAYS IN YOUR ENROLLMENT

To avoid delays in the enrollment process, you should:

- Complete all required sections.
- Ensure that the correspondence address shown in Section 2 is the supplier's address.
- Enter your NPI in the applicable sections.
- Enter all applicable dates.
- Send the completed application with all supporting documentation to your designated fee-for-service contractor.

ADDITIONAL INFORMATION

For additional information regarding the Medicare enrollment process, visit *www.cms.hhs.gov/MedicareProviderSupEnroll.*

The fee-for-service contractor may request, at any time during the enrollment process, documentation to support and validate information reported on the application. You are responsible for providing this documentation in a timely manner.

The information you provide on this form will not be shared. It is protected under 5 U.S.C. Section 552(b)(4) and/or (b)(6), respectively. For more information, see the last page of this application to read the Privacy Act Statement.

MAIL YOUR APPLICATION

The Medicare fee-for-service contractor (also referred to as a carrier or a Medicare administrative contractor) that services your State is responsible for processing your enrollment application. To locate the mailing address for your fee-for-service contractor, go to *www.cms.hhs.gov/MedicareProviderSupEnroll*.

SECTION 1: BASIC INFORMATION

This section captures information regarding the reason you are submitting this application. Read this section in full prior to indicating the reason for submission on page 4.

NEW ENROLLEES TO MEDICARE

If you are:

- Enrolling in the Medicare program for the first time with this particular Medicare fee-for-service contractor.
- A physician assistant whose services are reimbursed through your employer would complete this application. However, he/she would not complete the CMS 855R.

NOTE: A physician assistant should only complete Sections 1, 2, 3, 13, 15 and 17, and should report all employers in Section 2E.

ENROLLED MEDICARE SUPPLIERS

The following actions apply to Medicare suppliers already enrolled in the program.

Enrolling with another fee-for-service contractor

If you are already enrolled with a Medicare fee-for-service contractor but are establishing a practice location in another fee-for-service contractor's jurisdiction.

Reactivation

To reactivate your Medicare billing privileges, submit this enrollment application. In addition, you must be able to submit a valid claim and meet all current requirements for your supplier type.

Voluntary Termination

You should voluntarily terminate your Medicare enrollment if you:

- Will no longer be rendering services to Medicare patients, or
- Are planning to cease (or have ceased) operations.

Change of Information

If you are adding, deleting, or changing information that you previously reported to Medicare.

If you are already enrolled in Medicare and are not receiving Medicare payments via EFT, any change to your enrollment information will require you to submit a CMS-588 form. All future payments will then be made via EFT.

Changes in your existing enrollment data must be reported to the fee-for-service contractor in accordance with 42 C.F.R. § 424.516.

Revalidation

CMS may require you to submit or update your enrollment information. The fee-for-service contractor will notify you when it is time for you to revalidate your enrollment information. Do not submit a revalidation application until you have been contacted by the fee-for-service contractor.

SECTION 1: BASIC INFORMATION

A. Check one box and complete the required sections.

Since physician assistants do not complete Section 4, all physician assistants must furnish their Medicare Identification Number (if issued) and their NPI here:

Medicare Identification Number(s):_____ NPI:_____

If you are reassigning all of your Medicare benefits per section 4B1 of this application, furnish your Medicare Identification Number (if issued) and your individual (Type 1) NPI here:

Medicare Identification Number(s):_____ NPI:_____

REASON FOR APPLICATION	BILLING NUMBER INFORMATION	REQUIRED SECTIONS
☐ You are a **new enrollee** in Medicare	Enter your Medicare Identification Number *(if issued)* and the NPI you would like to link to this number in Section 4.	**Complete all sections**
☐ You are **enrolling with another fee-for-service contractor**	Enter your Medicare Identification Number *(if issued)* and the NPI you would like to link to this number in Section 4.	**Complete all sections**
☐ You are **reactivating** your Medicare enrollment	Enter your Medicare Identification Number *(if issued)* and the NPI you would like to link to this number in Section 4.	**Complete all sections**
☐ You are **voluntarily terminating** your Medicare enrollment	Effective Date of Termination Medicare Identification Number(s) to Terminate *(if issued)*: _____ National Provider Identifier *(if issued)*: _____	Sections **1A, 13** and **15** Physician Assistants must complete Sections **1A, 2F, 13** and **15** Employers terminating Physician Assistants must complete Sections **1A, 2G, 13** and **15**

SECTION 1: BASIC INFORMATION (Continued)

☐ You are **changing** your Medicare information	Medicare Identification Number *(if issued)*: _____ NPI: _____	Go to Section **1B**
☐ You are **revalidating** your Medicare enrollment	Enter your Medicare Identification Number *(if issued)* and the NPI you would like to link to this number in Section 4.	**Complete all sections**

B. Check all that apply and complete the required sections.

	REQUIRED SECTIONS
☐ Identifying Information	**1, 2** (complete only those sections that are changing), **3, 13** and **15**
☐ Final Adverse Actions/Convictions	**1, 2A, 3, 13 and 15**
☐ Practice Location Information, Payment Address and Medical Record Storage Information	**1, 2A, 3, 4** (complete only those sections that are changing), **13** and **15**
☐ Individuals Having Managing Control	**1, 2A, 3, 6, 13,** and **15**
☐ Billing Agency Information	**1, 2A, 3, 8** (complete only those sections that are changing), **13** and **15**

SECTION 2: IDENTIFYING INFORMATION

A. Personal Information: Your name, date of birth, and social security number must coincide with the information on your social security record.

1. First Name	Middle Initial	Last Name	Jr., Sr., M.D., D.O., etc.
2. Other Name, First	Middle Initial	Last Name	Jr., Sr., M.D., D.O., etc.

Type of Other Name

☐ Former or Maiden Name ☐ Professional Name ☐ Other *(Describe)*:_____

Date of Birth *(mm/dd/yyyy)*	State of Birth	Country of Birth

3. Gender ☐ Male ☐ Female	4. Social Security Number	
Medical or other Professional School *(Training Institution, if non-MD)*	Year of Graduation *(yyyy)*	DEA Number *(if applicable)*

License Information

☐ License Not Applicable

License Number	State Where Issued
Effective Date *(mm/dd/yyyy)*	Expiration/Renewal Date *(mm/dd/yyyy)*

Certification Information

☐ Certification Not Applicable

Certification Number	State Where Issued
Effective Date *(mm/dd/yyyy)*	Expiration/Renewal Date *(mm/dd/yyyy)*

B. Correspondence Address

Provide contact information for the person shown in Section 2A above. Once enrolled, the information provided below will be used by the fee-for-service contractor if it needs to contact you directly. This address cannot be a billing agency's address.

Mailing Address Line 1 *(Street Name and Number)*

Mailing Address Line 2 *(Suite, Room, etc.)*

City/Town	State	ZIP Code + 4

Telephone Number	Fax Number *(if applicable)*	E-mail Address *(if applicable)*

SECTION 2: IDENTIFYING INFORMATION (Continued)

C. Resident/Fellow Status

1. Are you currently in an approved training program as:
   a. A resident? ☐ YES ☐ NO
   b. In a fellowship program? ☐ YES ☐ NO

   • If NO, skip to Section 2D.
   • If YES to either of the above questions, provide the name and address of the facility where you are a resident or fellow on the following lines:

_____

_____

_____

2. Are the services that you render at the facility shown in Section 2C1 part of your requirements for graduation from a formal residency or fellowship program? ☐ YES ☐ NO

   Date of Completion:_____. If your completion date is prior to the beginning date for your practice in Section 4, skip to Section 2D.

3. Do you also render services at other facilities or practice locations? IF YES, you must report these practice locations in Section 4. ☐ YES ☐ NO

4. Are the services that you render in any of the practice locations you will be reporting in Section 4 part of your requirements for graduation from a residency or fellowship program? ☐ YES ☐ NO

IF YES, has the teaching hospital reported in Section 2C1 above agreed to incur all or substantially all of the costs of training in the non-hospital facility. ☐ YES ☐ NO

SECTION 2: IDENTIFYING INFORMATION (Continued)

D. Medical Specialties

1. PHYSICIAN SPECIALTY

Designate your primary specialty and all secondary specialty(s) below using:
P=Primary S=Secondary

You may select only one primary specialty. You may select multiple secondary specialties. A physician must meet all Federal and State requirements for the type of specialty(s) checked.

- ☐ Addiction medicine
- ☐ Allergy/Immunology
- ☐ Anesthesiology
- ☐ Cardiac surgery
- ☐ Cardiovascular disease (Cardiology)
- ☐ Chiropractic
- ☐ Colorectal surgery (Proctology)
- ☐ Critical care (Intensivists)
- ☐ Dermatology
- ☐ Diagnostic radiology
- ☐ Emergency medicine
- ☐ Endocrinology
- ☐ Family practice
- ☐ Gastroenterology
- ☐ General practice
- ☐ General surgery
- ☐ Geriatric medicine
- ☐ Gynecological oncology
- ☐ Hand surgery
- ☐ Hematology
- ☐ Hematology/Oncology
- ☐ Infectious disease
- ☐ Internal medicine
- ☐ Interventional Pain Management
- ☐ Interventional radiology
- ☐ Maxillofacial surgery
- ☐ Medical oncology
- ☐ Nephrology
- ☐ Neurology
- ☐ Neuropsychiatry
- ☐ Neurosurgery
- ☐ Nuclear medicine
- ☐ Obstetrics/Gynecology
- ☐ Ophthalmology
- ☐ Optometry
- ☐ Oral surgery (Dentist only)
- ☐ Orthopedic surgery
- ☐ Osteopathic manipulative therapy
- ☐ Otolaryngology
- ☐ Pain Management
- ☐ Pathology
- ☐ Pediatric medicine
- ☐ Peripheral vascular disease
- ☐ Physical medicine and rehabilitation
- ☐ Plastic and reconstructive surgery
- ☐ Podiatry
- ☐ Preventive medicine
- ☐ Psychiatry
- ☐ Pulmonary disease
- ☐ Radiation oncology
- ☐ Rheumatology
- ☐ Surgical oncology
- ☐ Thoracic surgery
- ☐ Urology
- ☐ Vascular surgery
- ☐ Undefined physician type *(Specify)*:_____

SECTION 2: IDENTIFYING INFORMATION (Continued)

2. NON–PHYSICIAN SPECIALTY

If you are a non-physician practitioner, check the appropriate box to indicate your specialty.

All non-physician practitioners must meet specific licensing, educational, and work experience requirements. If you need information concerning the specific requirements for your specialty, contact the Medicare fee-for-service contractor.

Check only one of the following: If you want to enroll as more than one non-physician specialty type, you must submit a separate CMS-855I application for each.

- ☐ Anesthesiology assistant
- ☐ Audiologist
- ☐ Certified nurse midwife
- ☐ Certified registered nurse anesthetist
- ☐ Clinical nurse specialist
- ☐ Clinical social worker
- ☐ Mass immunization roster biller
- ☐ Nurse practitioner
- ☐ Occupational therapist in private practice
- ☐ Physical therapist in private practice
- ☐ Physician assistant
- ☐ Psychologist, clinical
- ☐ Psychologist billing independently
- ☐ Registered dietitian or nutrition professional
- ☐ Speech Language Pathologist
- ☐ Undefined non-physician practitioner type *(Specify)*:

_____

_____

_____

SECTION 2: IDENTIFYING INFORMATION (Continued)

E. Physician Assistants: Establishing Employment Arrangement(s)

Employer's Name	Effective Date of Employment	Employer's Medicare Identification Number *(if issued)*	Employer's NPI

F. Physician Assistants: Terminating Employment Arrangement(s)

Complete this section if you are a physician assistant discontinuing your employment with a practice.

Employer's Name	Effective Date of Departure	Employer's Medicare Identification Number *(if issued)*	Employer's NPI

G. Employer Terminating Employment Arrangement With One or More Physician Assistants

This section should be used by an individual who has incorporated or is a sole proprietor, and who is discontinuing their employment arrangement with a physician assistant.

Physician Assistant's Name	Effective Date of Departure	Physician Assistant's Medicare Identification Number *(if issued)*	Physician Assistant's NPI

SECTION 2: IDENTIFYING INFORMATION (Continued)

H. Clinical Psychologists

Do you hold a doctoral degree in psychology? ☐ YES ☐ NO

If YES, furnish the field of your psychology degree_____

Attach a copy of the degree with this application.

I. Psychologists Billing Independently

1. Do you render services of your own responsibility free from the administrative control of an employer such as a physician, institution, or agency? ☐ YES ☐ NO
2. Do you treat your own patients? ☐ YES ☐ NO
3. Do you have the right to bill directly, and to collect and retain the fee for your services? ☐ YES ☐ NO
4. Is this private practice located in an institution? ☐ YES ☐ NO

   If YES to question 4 above, please answer questions "a" and "b" below.

   a) If your private practice is located in an institution, is your office confined to a separately identified part of the facility that is used solely as your office and cannot be construed as extending throughout the entire institution? ☐ YES ☐ NO

   b) If your private practice is located in an institution, are your services also rendered to patients from outside the institution or facility where your office is located? ☐ YES ☐ NO

J. Physical Therapists/Occupational Therapists in Private Practice (PT/OT)

The following questions only apply to your individual practice. They do not apply if you are reassigning all of your benefits to a group/organization.

1. Are all of your PT/OT services only rendered in the patients' homes? ☐ YES ☐ NO
2. Do you maintain private office space? ☐ YES ☐ NO
3. Do you own, lease, or rent your private office space? ☐ YES ☐ NO
4. Is this private office space used exclusively for your private practice? ☐ YES ☐ NO
5. Do you provide PT/OT services outside of your office and/or patients' homes? ☐ YES ☐ NO

If you respond YES to any of the questions 2–5 above, attach a copy of the lease agreement that gives you exclusive use of the facility for PT/OT services.

K. Nurse Practitioners and Certified Clinical Nurse Specialists

Are you an employee of a Medicare skilled nursing facility (SNF) or of another entity that has an agreement to provide nursing services to a SNF? ☐ YES ☐ NO

If yes, include the SNF's name and address.

Name

Street Address

City	State	Zip

SECTION 3: FINAL ADVERSE ACTIONS/CONVICTIONS

This section captures information on final adverse actions, such as convictions, exclusions, revocations, and suspensions. All applicable final adverse actions must be reported, regardless of whether any records were expunged or any appeals are pending. Enrolled suppliers are required to report all Final Adverse Actions/Convictions within 30 days of the reportable event.

FINAL ADVERSE ACTIONS THAT MUST BE REPORTED

Convictions

1. The provider, supplier, or any owner of the provider or supplier was, within the last 10 years preceding enrollment or revalidation of enrollment, convicted of a Federal or State felony offense that CMS has determined to be detrimental to the best interests of the program and its beneficiaries. Offenses include:

   Felony crimes against persons and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pre-trial diversions; financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pre-trial diversions; any felony that placed the Medicare program or its beneficiaries at immediate risk (such as a malpractice suit that results in a conviction of criminal neglect or misconduct); and any felonies that would result in a mandatory exclusion under Section 1128(a) of the Social Security Act.

2. Any misdemeanor conviction, under Federal or State law, related to: (a) the delivery of an item or service under Medicare or a State health care program, or (b) the abuse or neglect of a patient in connection with the delivery of a health care item or service.
3. Any misdemeanor conviction, under Federal or State law, related to theft, fraud, embezzlement, breach of fiduciary duty, or other financial misconduct in connection with the delivery of a health care item or service.
4. Any felony or misdemeanor conviction, under Federal or State law, relating to the interference with or obstruction of any investigation into any criminal offense described in 42 C.F.R. Section 1001.101 or 1001.201.
5. Any felony or misdemeanor conviction, under Federal or State law, relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

Exclusions, Revocations, or Suspensions

1. Any revocation or suspension of a license to provide health care by any State licensing authority. This includes the surrender of such a license while a formal disciplinary proceeding was pending before a State licensing authority.
2. Any revocation or suspension of accreditation.
3. Any suspension or exclusion from participation in, or any sanction imposed by, a Federal or State health care program, or any debarment from participation in any Federal Executive Branch procurement or non-procurement program.
4. Any current Medicare payment suspension under any Medicare billing number.
5. Any Medicare revocation of any Medicare billing number.

SECTION 3: FINAL ADVERSE ACTIONS/CONVICTIONS (Continued)

FINAL ADVERSE HISTORY

1. Have you, under any current or former name or business identity, ever had a final adverse action listed on page 12 of this application imposed against you?

   ☐ YES–Continue Below ☐ NO–Skip to Section 4

2. If yes, report each final adverse action, when it occurred, the Federal or State agency or the court/administrative body that imposed the action, and the resolution, if any.

   Attach a copy of the final adverse action documentation and resolution.

Final Adverse Action	Date	Taken By	Resolution

SECTION 4: PRACTICE LOCATION INFORMATION

A. Establishing a Professional Corporation, Professional Association, Limited Liability Company, etc.

If you are the sole owner of a professional corporation, a professional association, or a limited liability company, and will bill Medicare through this business entity, complete this section 4A, skip to Section 4C, and complete the remainder of the application with information about your business entity.

Legal Business Name as Reported to the Internal Revenue Service	Tax Identification Number
Medicare Identification Number *(if issued)*	NPI
Incorporation Date *(mm/dd/yyyy) (if applicable)*	State Where Incorporated *(if applicable)*

FINAL ADVERSE HISTORY

1. Has your organization, under any current or former name or business identity, ever had any of the final adverse actions listed on page 12 of this application imposed against it?

   ☐ YES–Continue Below ☐ NO–Skip to Section 4

2. If yes, report each final adverse action, when it occurred, the Federal or State agency or the court/administrative body that imposed the action, and the resolution, if any.

   Attach a copy of the final adverse action documentation and resolution.

Final Adverse Action	Date	Taken By	Resolution
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

If you are the sole owner of a professional corporation, a professional association, or a limited liability company, and will bill Medicare through this business entity, you do not need to complete a CMS-855R that reassigns your benefits to the business entity.

B. Individual Affiliations

Complete this section with information about your private practice and group affiliations.

Furnish the requested information about each group/organization to which you will reassign your benefits. In addition, either you or each group/organization reported in this section must complete and submit a CMS 855R(s) (Individual Reassignment of Benefits) with this application. Reassigning benefits means that you are authorizing the group/organization to bill and receive payment from Medicare for the services you have rendered at the group/organization's practice location.

If you are an individual who is reassigning all of your benefits to a group, neither you nor the group needs to submit a CMS-588 (Electronic Funds Transfer Authorized Agreement) to facilitate that reassignment.

SECTION 4: PRACTICE LOCATION INFORMATION (Continued)

1. If you are reassigning **all** of your payments to another group or organization furnish the name, Medicare identification number(s) and NPI of each group or organization below and proceed to Section 13.

2. If **any** of your payments are part of your private practice and a group or organization furnish the name and Medicare identification number(s) and NPI of each group or organization below and continue to Section 4C (where you will enter your private practice information).

3. If you are **not** reassigning all or any of your payments to another group or organization, **skip** to Section 4C with information about your private practice.

a) Name of Group/Organization	Medicare Identification Number *(if issued)*	National Provider Identifier
b) Name of Group/Organization	Medicare Identification Number *(if issued)*	National Provider Identifier
c) Name of Group/Organization	Medicare Identification Number *(if issued)*	National Provider Identifier
d) Name of Group/Organization	Medicare Identification Number *(if issued)*	National Provider Identifier
e) Name of Group/Organization	Medicare Identification Number *(if issued)*	National Provider Identifier

C. Practice Location Information

- If you completed Section 4A, complete Section 4C through Section 17 for your business.
- All locations disclosed on claims forms should be identified in this section as practice locations.
- Complete this section for each of your practice locations where you render services to Medicare beneficiaries. However, you should only report those practice locations within the jurisdiction of the Medicare fee-for-service contractor to which you will submit this application. If you render services in a hospital and/or other health care facility, furnish the name and address of that hospital or facility.
- Each practice location must be a specific street address as recorded by the United States Postal Service. Do not report a P.O. Box.
- If you only render services in patients' homes (house calls), you may supply your home address in this section if you do not have an office. In Section 4H, explain that this address is for administrative purposes only and that all services are rendered in patients' homes.
- If you render services in a retirement or assisted living community, complete this section with the names, telephone numbers and addresses of those communities.

If you have a CLIA number and/or FDA/Radiology Certification Number for this practice location, provide that information and submit a copy of the most current CLIA and FDA certification for each practice location reported.

SECTION 4: PRACTICE LOCATION INFORMATION (Continued)

If you or your organization sees patients in more than one practice location, copy and complete this Section 4C for each location.

If you are changing, adding, or deleting information, check the applicable box, furnish the effective date, and complete the appropriate fields in this section.

CHECK ONE	☐ CHANGE	☐ ADD	☐ DELETE
DATE (mm/dd/yyyy)			

If you are enrolling for the first time, or if you are adding a new practice location, the date you provide should be the date you saw your first Medicare patient at this location.

Practice Location Name *("Doing Business As" name if different from Legal Business Name)*

Practice Location Street Address Line 1 *(Street Name and Number – NOT a P.O. Box)*

Practice Location Street Address Line 2 *(Suite, Room, etc.)*

City/Town	State	ZIP Code + 4

Telephone Number	Fax Number *(if applicable)*	E-mail Address *(if applicable)*

Medicare Identification Number *(if issued)*	NPI

Date you saw your first Medicare patient at this practice location

Is this practice location a:

☐ Private practice office setting ☐ Retirement/assisted living community

☐ Hospital ☐ Other health care facility *(Specify)*:_____

CLIA Number for this location *(if applicable)*	FDA/Radiology (Mammography) Certification Number for this location *(if issued)*

SECTION 4: PRACTICE LOCATION INFORMATION (Continued)

D. Rendering Services In Patients' Homes

List the city/town, State, and ZIP code for all locations where health care services are rendered in patients' homes. If you provide health care services in more than one State and those States are serviced by different Medicare fee-for-service contractors, complete a separate enrollment application (CMS-855I) for each Medicare fee-for-service contractor's jurisdiction.

If you are changing, adding, or deleting information, check the applicable box, furnish the effective date, and complete the appropriate fields in this section.

CHECK ONE	☐ CHANGE	☐ ADD	☐ DELETE
DATE (mm/dd/yyyy)			

INITIAL REPORTING AND/OR ADDITIONS

If you are reporting or adding an entire State, it is not necessary to report each city/town. Simply check the box below and specify the State.

☐ Entire State of _____

If services are provided in selected cities/towns, provide the locations below. Only list ZIP codes if you are not servicing the entire city/town.

City/Town	State	ZIP Code

DELETIONS

If you are deleting an entire State, it is not necessary to report each city/town. Simply check the box below and specify the State.

☐ Entire State of _____

If services are provided in selected cities/towns, provide the locations below. Only list ZIP codes if you are not servicing the entire city/town.

City/Town	State	ZIP Code

SECTION 4: PRACTICE LOCATION INFORMATION (Continued)

E. Where Do You Want Remittance Notices or Special Payments Sent?

If you are changing, adding, or deleting information, check the applicable box, furnish the effective date, and complete the appropriate fields in this section.

CHECK ONE	☐ CHANGE	☐ ADD	☐ DELETE
DATE (mm/dd/yyyy)			

Medicare will issue payments via electronic funds transfer (EFT). Since payment will be made by EFT, the "Special Payments" address will indicate where all other payment information (e.g., remittance notices, special payments) are sent.

☐ "Special Payments" address is the same as the practice location (only one address is listed in Section 4C). Skip to Section 4F.

☐ "Special Payments" address is different than that listed in Section 4C, or multiple locations are listed. Provide address below.

Furnish the address where remittance notices and special payments should be sent for services rendered at the practice location(s) in Section 4C. Note that payments will be made in your name; if an entity is listed in Section 4A of this application, payments will be made in the organization's name.

"Special Payment" Address Line 1 *(PO Box or Street Name and Number)*

"Special Payment" Address Line 2 *(Suite, Room, etc.)*

City/Town	State	ZIP Code + 4

F. Employer ID Number Information

NOTE: If you are a sole proprietor and you want Medicare payments to be reported under your EIN, list it below. Unless indicated in this section, payments will be made to your SSN. You cannot use both an SSN and EIN. You can only use one EIN to bill Medicare.

To qualify for this payment arrangement, you:

- Must be a sole proprietor,
- Cannot reassign all of your Medicare payments, and,
- Want your payments to be made to your EIN. Furnish IRS documentation showing your EIN.

Employer Identification Number (EIN)

SECTION 4: PRACTICE LOCATION INFORMATION (Continued)

G. Where Do You Keep Patients' Medical Records?

If the patients' medical records are stored at a location other than the location shown in Section 4C, complete this section with the name and address of the storage location. This includes both current and former patients' records.

Post Office Boxes and drop boxes are not acceptable as physical addresses where patients' records are maintained. The records must be your records, not those of another supplier. If this section is not completed, you are indicating that all records are stored at the practice locations reported in Section 4C.

If you are changing, adding, or deleting information, check the applicable box, furnish the effective date, and complete the appropriate fields in this section.

First Medical Record Storage Facility (for current and former patients)

CHECK ONE	☐ CHANGE	☐ ADD	☐ DELETE
DATE (mm/dd/yyyy)			

Storage Facility Address Line 1 *(Street Name and Number)*

Storage Facility Address Line 2 *(Suite, Room, etc.)*

City/Town	State	ZIP Code + 4

Second Medical Record Storage Facility (for current and former patients)

CHECK ONE	☐ CHANGE	☐ ADD	☐ DELETE
DATE (mm/dd/yyyy)			

Storage Facility Address Line 1 *(Street Name and Number)*

Storage Facility Address Line 2 *(Suite, Room, etc.)*

City/Town	State	ZIP Code + 4

H. Unique Circumstances

Explain any unique circumstances concerning your practice locations or the method by which you render health care services (e.g., you only render services in patients' homes [house calls only]).

SECTION 5: FOR FUTURE USE (This Section Not Applicable)

SECTION 6: INDIVIDUALS HAVING MANAGING CONTROL

This section captures information about all managing employees. A managing employee means a general manager, business manager, administrator, director, or other individual who exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operations of the supplier, either under contract or through some other arrangement, regardless of whether the individual is a W-2 employee of the supplier.

All managing employees at any of your practice locations shown in Section 4 must be reported in this section. If there is more than one managing employee, copy and complete this section as needed.

A. Managing Employee Identifying Information

If you are changing, adding, or deleting information, check the applicable box, furnish the effective date, and complete the appropriate fields in this section.

CHECK ONE	☐ CHANGE	☐ ADD	☐ DELETE
DATE (mm/dd/yyyy)			

1. First Name	Middle Initial	Last Name	Jr., Sr., etc.
2. Title		Date of Birth *(mm/dd/yyyy)*	
3. Social Security Number *(Required)*	Medicare Identification Number *(if issued)*	NPI *(if issued)*	

B. Final Adverse History

Complete this section for the individual reported in Section 6A above. If you are changing or adding information, check the "change" box, furnish the effective date, and complete the appropriate fields in this section.

☐ Change ☐ Effective Date:_____

1. Has this individual in Section 6A above, under any current or former name or business identity, ever had a final adverse action listed on page 12 of this application imposed against him/her?

☐ YES–Continue Below ☐ NO–Skip to Section 8

2. If yes, report each final adverse action, when it occurred, the Federal or State agency or court/administrative body that imposed the action, and the resolution, if any.

Final Adverse Action	Date	Taken By	Resolution

SECTION 7: FOR FUTURE USE (This Section Not Applicable)

SECTION 8: BILLING AGENCY INFORMATION

A billing agency is a company or individual that you contract with to prepare and submit your claims. If you use a billing agency, you are responsible for the claims submitted on your behalf.

CHECK HERE ☐ If this section does not apply and skip to Section 13.

Billing Agency Name and Address

If you are changing, adding, or deleting information, check the applicable box, furnish the effective date, and complete the appropriate fields in this section.

CHECK ONE	☐ CHANGE	☐ ADD	☐ DELETE
DATE (mm/dd/yyyy)			

Legal Business Name *(as Reported to the Internal Revenue Service)*	Tax ID Number or Social Security Number *(required)*

"Doing Business As" Name *(if applicable)*

Billing Agency Address Line 1 *(Street Name and Number)*

Billing Agency Address Line 2 *(Suite, Room, etc.)*

City/Town	State	ZIP Code + 4

Telephone Number	Fax Number *(if applicable)*	E-mail Address *(if applicable)*

SECTION 9: FOR FUTURE USE (This Section Not Applicable)

SECTION 10: FOR FUTURE USE (This Section Not Applicable)

SECTION 11: FOR FUTURE USE (This Section Not Applicable)

SECTION 12: FOR FUTURE USE (This Section Not Applicable)

SECTION 13: CONTACT PERSON

This section captures information regarding the person you would like for us to contact regarding this application. If no one is listed below, we will contact you directly.

First Name	Middle Initial	Last Name	Jr., Sr., etc.

Telephone Number	Fax Number *(if applicable)*	E-mail Address *(if applicable)*

Address Line 1 *(Street Name and Number)*

Address Line 2 *(Suite, Room, etc.)*

City/Town	State	ZIP Code + 4

SECTION 14: PENALTIES FOR FALSIFYING INFORMATION

This section explains the penalties for deliberately furnishing false information in this application to gain or maintain enrollment in the Medicare program.

1. 1.18 U.S.C. § 1001 authorizes criminal penalties against an individual who, in any matter within the jurisdiction of any department or agency of the United States, knowingly and willfully falsifies, conceals or covers up by any trick, scheme or device a material fact, or makes any false, fictitious, or fraudulent statements or representations, or makes any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry. Individual offenders are subject to fines of up to $250,000 and imprisonment for up to five years. Offenders that are organizations are subject to fines of up to $500,000 (18 U.S.C. § 3571). Section 3571(d) also authorizes fines of up to twice the gross gain derived by the offender if it is greater than the amount specifically authorized by the sentencing statute.

2. Section 1128B(a)(1) of the Social Security Act authorizes criminal penalties against any individual who, "knowingly and willfully," makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under a Federal health care program. The offender is subject to fines of up to $25,000 and/or imprisonment for up to five years.

3. The Civil False Claims Act, 31 U.S.C. § 3729, imposes civil liability, in part, on any person who:
   a) knowingly presents, or causes to be presented, to an officer or any employee of the United States Government a false or fraudulent claim for payment or approval;
   b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; or
   c) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

   The Act imposes a civil penalty of $5,000 to $10,000 per violation, plus three times the amount of damages sustained by the Government

4. Section 1128A(a)(1) of the Social Security Act imposes civil liability, in part, on any person (including an organization, agency or other entity) that knowingly presents or causes to be presented to an officer, employee, or agent of the United States, or of any department or agency thereof, or of any State agency…a claim…that the Secretary determines is for a medical or other item or service that the person knows or should know:
   a) was not provided as claimed; and/or
   b) the claim is false or fraudulent.

   This provision authorizes a civil monetary penalty of up to $10,000 for each item or service, an assessment of up to three times the amount claimed, and exclusion from participation in the Medicare program and State health care programs.

5. 18 U.S.C. 1035 authorizes criminal penalties against individuals in any matter involving a health care benefit program who knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact; or makes any materially false, fictitious, or fraudulent statements or representations, or makes or uses any materially false fictitious, or fraudulent statement or entry, in connection with the delivery of or payment for health care benefits, items or services. The individual shall be fined or imprisoned up to 5 years or both.

SECTION 14: PENALTIES FOR FALSIFYING INFORMATION (Continued)

6. 18 U.S.C. 1347 authorizes criminal penalties against individuals who knowing and willfully execute, or attempt, to executive a scheme or artifice to defraud any health care benefit program, or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by or under the control of any, health care benefit program in connection with the delivery of or payment for health care benefits, items, or services. Individuals shall be fined or imprisoned up to 10 years or both. If the violation results in serious bodily injury, an individual will be fined or imprisoned up to 20 years, or both. If the violation results in death, the individual shall be fined or imprisoned for any term of years or for life, or both.

7. The government may assert common law claims such as "common law fraud," "money paid by mistake," and "unjust enrichment."

   Remedies include compensatory and punitive damages, restitution, and recovery of the amount of the unjust profit.

SECTION 15: CERTIFICATION STATEMENT

As an individual practitioner, you are the only person who can sign this application. The authority to sign the application on your behalf may not be delegated to any other person.

The Certification Statement contains certain standards that must be met for initial and continuous enrollment in the Medicare program. Review these requirements carefully.

By signing the Certification Statement, you agree to adhere to all of the requirements listed therein and acknowledge that you may be denied entry to or revoked from the Medicare program if any requirements are not met.

Certification Statement

You MUST sign and date the certification statement below in order to be enrolled in the Medicare program. In doing so, you are attesting to meeting and maintaining the Medicare requirements stated below.

I, the undersigned, certify to the following:

1. I have read the contents of this application, and the information contained herein is true, correct, and complete. If I become aware that any information in this application is not true, correct, or complete, I agree to notify the Medicare fee-for-service contractor of this fact immediately.
2. I authorize the Medicare contractor to **verify** the information contained herein. I agree to notify the Medicare contractor of a change in ownership, practice location and/or Final Adverse Action within 30 days of the reportable event. In addition, I agree to notify the Medicare contractor of any other changes to the information to this form within 90 days of the effective date of change. I understand that any change to my status as an individual practitioner may require the submission of a new application. I understand that any change in business structure of this supplier may require the submission of a new application.
3. I have read and understand the Penalties for Falsifying Information, as printed in this application. I understand that any deliberate omission, misrepresentation, or falsification of any information contained in this application or contained in any communication supplying information to Medicare, or any deliberate alteration of any text on this application form, may be punished by criminal, civil, or administrative penalties including, but not limited to, the denial or revocation of Medicare billing privileges, and/or the imposition of fines, civil damages, and/or imprisonment.
4. I agree to abide by the Medicare laws, regulations and program instructions that apply to me or to the organization listed in Section 4A of this application. The Medicare laws, regulations, and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.
5. Neither I, nor any managing employee listed on this application, is currently sanctioned, suspended, debarred, or excluded by the Medicare or State Health Care Program, e.g., Medicaid program, or any other Federal program, or is otherwise prohibited from providing services to Medicare or other Federal program beneficiaries.
6. I agree that any existing or future overpayment made to me (or to the organization listed in Section 4A of this application) by the Medicare program may be recouped by Medicare through the withholding of future payments.
7. I understand that the Medicare identification number issued to me can only be used by me or by a provider or supplier to whom I have reassigned my benefits under current Medicare regulations, when billing for services rendered by me.
8. I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.
9. I further certify that I am the individual practitioner who is applying for Medicare billing privileges.

SECTION 15: CERTIFICATION STATEMENT (Continued)

First Name	Middle Initial	Last Name	M.D., D.O., etc.
Practitioner Signature *(First, Middle, Last Name, Jr., Sr., M.D., D.O., etc.)*			Date Signed *(mm/dd/yyyy)*

All signatures must be original and signed in ink (blue ink preferred). Applications with signatures deemed not original will not be processed. Stamped, faxed or copied signatures will not be accepted.

SECTION 16: FOR FUTURE USE (This Section Not Applicable)

SECTION 17: SUPPORTING DOCUMENTS

This section lists the documents that, if applicable, must be submitted with this enrollment application. For changes, only submit documents that are applicable to the change requested. **The fee-for-service contractor may request, at any time during the enrollment process, documentation to support or validate information reported on the application.**

MANDATORY FOR ALL PROVIDER/SUPPLIER TYPES

☐ Completed Form CMS-588, for Electronic Funds Transfer Authorization Agreement.
NOTE: If a supplier already receives payments electronically and is not making a change to his/her banking information, the CMS-588 is not required. (Moreover, physicians and non-physician practitioners who are reassigning all of their payments to another entity are not required to submit the CMS-588.)

MANDATORY, IF APPLICABLE

☐ Copy(s) of all final adverse action documentation (e.g., notifications, resolutions, and reinstatement letters).

☐ Completed Form CMS-460, Medicare Participating Physician or Supplier Agreement.

☐ Completed Form CMS-855R, Individual Reassignment of Medicare Benefits.

☐ Statement in writing from the bank. If Medicare payment due a supplier of services is being sent to a bank (or similar financial institution) where the supplier has a lending relationship (that is, any type of loan), then the supplier must provide a statement in writing from the bank (which must be in the loan agreement) that the bank has agreed to waive its right of offset for Medicare receivables.

MEDICARE SUPPLIER ENROLLMENT APPLICATION PRIVACY ACT STATEMENT

The Centers for Medicare and Medicaid Services (CMS) is authorized to collect the information requested on this form by sections 1124(a)(1), 1124A(a)(3), 1128, 1814, 1815, 1833(e), and 1842(r) of the Social Security Act [42 U.S.C. §§ 1320a-3(a)(1), 1320a-7, 1395f, 1395g, 1395(l)(e), and 1395u(r)] and section 31001(1) of the Debt Collection Improvement Act [31 U.S.C. § 7701(c)].

The purpose of collecting this information is to determine or verify the eligibility of individuals and organizations to enroll in the Medicare program as suppliers of goods and services to Medicare beneficiaries and to assist in the administration of the Medicare program. This information will also be used to ensure that no payments will be made to providers who are excluded from participation in the Medicare program. All information on this form is required, with the exception of those sections marked as "optional" on the form. Without this information, the ability to make payments will be delayed or denied.

The information collected will be entered into the Provider Enrollment, Chain and Ownership System (PECOS), and the system number 09-70-0525 titled Unique Physician/Practitioner Identification Number (UPIN) System (published in Vol. 61 of the Federal Register at page 20,528 (May 7, 1996)). The information in this application will be disclosed according to the routine uses described below.

Information from these systems may be disclosed under specific circumstances to:

1. CMS contractors to carry out Medicare functions, collating or analyzing data, or to detect fraud or abuse;
2. A congressional office from the record of an individual health care provider in response to an inquiry from the congressional office at the written request of that individual health care practitioner;
3. The Railroad Retirement Board to administer provisions of the Railroad Retirement or Social Security Acts;
4. Peer Review Organizations in connection with the review of claims, or in connection with studies or other review activities, conducted pursuant to Part B of Title XVIII of the Social Security Act;
5. To the Department of Justice or an adjudicative body when the agency, an agency employee, or the United States Government is a party to litigation and the use of the information is compatible with the purpose for which the agency collected the information;
6. To the Department of Justice for investigating and prosecuting violations of the Social Security Act, to which criminal penalties are attached;
7. To the American Medical Association (AMA), for the purpose of attempting to identify medical doctors when the Unique Physician Identification Number Registry is unable to establish identity after matching contractor submitted data to the data extract provided by the AMA;
8. An individual or organization for a research, evaluation, or epidemiological project related to the prevention of disease or disability, or to the restoration or maintenance of health;
9. Other Federal agencies that administer a Federal health care benefit program to enumerate/enroll providers of medical services or to detect fraud or abuse;
10. State Licensing Boards for review of unethical practices or non-professional conduct;
11. States for the purpose of administration of health care programs; and/or
12. Insurance companies, self insurers, health maintenance organizations, multiple employer trusts, and other health care groups providing health care claims processing, when a link to Medicare or Medicaid claims is established, and data are used solely to process supplier's health care claims.

The enrolling supplier should be aware that the Computer Matching and Privacy Protection Act of 1988 (P.L. 100-503) amended the Privacy Act, 5 U.S.C. § 552a, to permit the government to verify information through computer matching.

Protection of Proprietary Information

Privileged or confidential commercial or financial information collected in this form is protected from public disclosure by Federal law 5 U.S.C. § 552(b)(4) and Executive Order 12600.

Protection of Confidential Commercial and/or Sensitive Personal Information

If any information within this application (or attachments thereto) constitutes a trade secret or privileged or confidential information (as such terms are interpreted under the Freedom of Information Act and applicable case law), or is of a highly sensitive personal nature such that disclosure would constitute a clearly unwarranted invasion of the personal privacy of one or more persons, then such information will be protected from release by CMS under 5 U.S.C. §§ 552(b)(4) and/or (b)(6), respectively.

EXHIBIT K

1500

HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE 08/05

PICA

PICA

CARRIER

PATIENT AND INSURED INFORMATION

1. MEDICARE (Medicare #) MEDICAID (Medicaid #) TRICARE CHAMPUS (Sponsor's SSN) CHAMPVA (Member ID#) GROUP HEALTH PLAN (SSN or ID) FECA BLK LUNG (SSN) OTHER (ID)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. PATIENT STATUS Single Married Other Employed Full-Time Student Part-Time Student

CITY STATE

ZIP CODE TELEPHONE (Include Area Code) ( )

ZIP CODE TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. OTHER INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. AUTO ACCIDENT? PLACE (State) YES NO

b. EMPLOYER'S NAME OR SCHOOL NAME

c. EMPLOYER'S NAME OR SCHOOL NAME

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. RESERVED FOR LOCAL USE

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, return to and complete item 9 a-d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

PHYSICIAN OR SUPPLIER INFORMATION

14. DATE OF CURRENT: MM DD YY ILLNESS (First symptom) OR INJURY (Accident) OR PREGNANCY(LMP)

15. IF PATIENT HAS HAD SAME OR SIMILAR ILLNESS. GIVE FIRST DATE MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM MM DD YY TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM MM DD YY TO

19. RESERVED FOR LOCAL USE

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate Items 1, 2, 3 or 4 to Item 24E by Line)

1. 3.

2. 4.

22. MEDICAID RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1								NPI	
2								NPI	
3								NPI	
4								NPI	
5								NPI	
6								NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. BALANCE DUE $

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

BECAUSE THIS FORM IS USED BY VARIOUS GOVERNMENT AND PRIVATE HEALTH PROGRAMS, SEE SEPARATE INSTRUCTIONS ISSUED BY APPLICABLE PROGRAMS.

NOTICE: Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties.

REFERS TO GOVERNMENT PROGRAMS ONLY

MEDICARE AND CHAMPUS PAYMENTS: A patient's signature requests that payment be made and authorizes release of any information necessary to process the claim and certifies that the information provided in Blocks 1 through 12 is true, accurate and complete. In the case of a Medicare claim, the patient's signature authorizes any entity to release to Medicare medical and nonmedical information, including employment status, and whether the person has employer group health insurance, liability, no-fault, worker's compensation or other insurance which is responsible to pay for the services for which the Medicare claim is made. See 42 CFR 411.24(a). If item 9 is completed, the patient's signature authorizes release of the information to the health plan or agency shown. In Medicare assigned or CHAMPUS participation cases, the physician agrees to accept the charge determination of the Medicare carrier or CHAMPUS fiscal intermediary as the full charge, and the patient is responsible only for the deductible, coinsurance and noncovered services. Coinsurance and the deductible are based upon the charge determination of the Medicare carrier or CHAMPUS fiscal intermediary if this is less than the charge submitted. CHAMPUS is not a health insurance program but makes payment for health benefits provided through certain affiliations with the Uniformed Services. Information on the patient's sponsor should be provided in those items captioned in "Insured"; i.e., items 1a, 4, 6, 7, 9, and 11.

BLACK LUNG AND FECA CLAIMS

The provider agrees to accept the amount paid by the Government as payment in full. See Black Lung and FECA instructions regarding required procedure and diagnosis coding systems.

SIGNATURE OF PHYSICIAN OR SUPPLIER (MEDICARE, CHAMPUS, FECA AND BLACK LUNG)

I certify that the services shown on this form were medically indicated and necessary for the health of the patient and were personally furnished by me or were furnished incident to my professional service by my employee under my immediate personal supervision, except as otherwise expressly permitted by Medicare or CHAMPUS regulations.

For services to be considered as "incident" to a physician's professional service, 1) they must be rendered under the physician's immediate personal supervision by his/her employee, 2) they must be an integral, although incidental part of a covered physician's service, 3) they must be of kinds commonly furnished in physician's offices, and 4) the services of nonphysicians must be included on the physician's bills.

For CHAMPUS claims, I further certify that I (or any employee) who rendered services am not an active duty member of the Uniformed Services or a civilian employee of the United States Government or a contract employee of the United States Government, either civilian or military (refer to 5 USC 5536). For Black-Lung claims, I further certify that the services performed were for a Black Lung-related disorder.

No Part B Medicare benefits may be paid unless this form is received as required by existing law and regulations (42 CFR 424.32).

NOTICE: Any one who misrepresents or falsifies essential information to receive payment from Federal funds requested by this form may upon conviction be subject to fine and imprisonment under applicable Federal laws.

NOTICE TO PATIENT ABOUT THE COLLECTION AND USE OF MEDICARE, CHAMPUS, FECA, AND BLACK LUNG INFORMATION
(PRIVACY ACT STATEMENT)

We are authorized by CMS, CHAMPUS and OWCP to ask you for information needed in the administration of the Medicare, CHAMPUS, FECA, and Black Lung programs. Authority to collect information is in section 205(a), 1862, 1872 and 1874 of the Social Security Act as amended, 42 CFR 411.24(a) and 424.5(a) (6), and 44 USC 3101;41 CFR 101 et seq and 10 USC 1079 and 1086; 5 USC 8101 et seq; and 30 USC 901 et seq; 38 USC 613; E.O. 9397.

The information we obtain to complete claims under these programs is used to identify you and to determine your eligibility. It is also used to decide if the services and supplies you received are covered by these programs and to insure that proper payment is made.

The information may also be given to other providers of services, carriers, intermediaries, medical review boards, health plans, and other organizations or Federal agencies, for the effective administration of Federal provisions that require other third parties payers to pay primary to Federal program, and as otherwise necessary to administer these programs. For example, it may be necessary to disclose information about the benefits you have used to a hospital or doctor. Additional disclosures are made through routine uses for information contained in systems of records.

FOR MEDICARE CLAIMS: See the notice modifying system No. 09-70-0501, titled, 'Carrier Medicare Claims Record,' published in the Federal Register, Vol. 55 No. 177, page 37549, Wed. Sept. 12, 1990, or as updated and republished.

FOR OWCP CLAIMS: Department of Labor, Privacy Act of 1974, "Republication of Notice of Systems of Records," Federal Register Vol. 55 No. 40, Wed Feb. 28, 1990, See ESA-5, ESA-6, ESA-12, ESA-13, ESA-30, or as updated and republished.

FOR CHAMPUS CLAIMS: PRINCIPLE PURPOSE(S): To evaluate eligibility for medical care provided by civilian sources and to issue payment upon establishment of eligibility and determination that the services/supplies received are authorized by law.

ROUTINE USE(S): Information from claims and related documents may be given to the Dept. of Veterans Affairs, the Dept. of Health and Human Services and/or the Dept. of Transportation consistent with their statutory administrative responsibilities under CHAMPUS/CHAMPVA; to the Dept. of Justice for representation of the Secretary of Defense in civil actions; to the Internal Revenue Service, private collection agencies, and consumer reporting agencies in connection with recoupment claims; and to Congressional Offices in response to inquiries made at the request of the person to whom a record pertains. Appropriate disclosures may be made to other federal, state, local, foreign government agencies, private business entities, and individual providers of care, on matters relating to entitlement, claims adjudication, fraud, program abuse, utilization review, quality assurance, peer review, program integrity, third-party liability, coordination of benefits, and civil and criminal litigation related to the operation of CHAMPUS.

DISCLOSURES: Voluntary; however, failure to provide information will result in delay in payment or may result in denial of claim. With the one exception discussed below, there are no penalties under these programs for refusing to supply information. However, failure to furnish information regarding the medical services rendered or the amount charged would prevent payment of claims under these programs. Failure to furnish any other information, such as name or claim number, would delay payment of the claim. Failure to provide medical information under FECA could be deemed an obstruction.

It is mandatory that you tell us if you know that another party is responsible for paying for your treatment. Section 1128B of the Social Security Act and 31 USC 3801-3812 provide penalties for withholding this information.

You should be aware that P.L. 100-503, the "Computer Matching and Privacy Protection Act of 1988", permits the government to verify information by way of computer matches.

MEDICAID PAYMENTS (PROVIDER CERTIFICATION)

I hereby agree to keep such records as are necessary to disclose fully the extent of services provided to individuals under the State's Title XIX plan and to furnish information regarding any payments claimed for providing such services as the State Agency or Dept. of Health and Human Services may request.

I further agree to accept, as payment in full, the amount paid by the Medicaid program for those claims submitted for payment under that program, with the exception of authorized deductible, coinsurance, co-payment or similar cost-sharing charge.

SIGNATURE OF PHYSICIAN (OR SUPPLIER): I certify that the services listed above were medically indicated and necessary to the health of this patient and were personally furnished by me or my employee under my personal direction.

NOTICE: This is to certify that the foregoing information is true, accurate and complete. I understand that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws.