IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA *Ex Rel.* Linda Nicholson Plaintiffs, vs. Lilian Spigelman M.D., Hephzibah Children's Association, and Sears Pharmacy, Defendants.	))))))))))))	Case No. 10 C 3361 The Honorable Gary Feinerman Magistrate Judge Sidney I. Schenkier

RESPONSE BY RELATOR NICHOLSON IN OPPOSITION TO DEFENDANTS' CONSOLIDATED MOTION TO DISMISS PURSUANT TO F.R.CIV.P. 12(B)6

Qui tam relator Nicholson opposes Defendants' Consolidated Motion to Dismiss Pursuant to F.R.Civ.P. 12(B)(6).

I. OVERVIEW

Relator Nicholson brought and pursues this case on behalf of the United States solely to earn her share in the recovery of monies paid by the United States for the Defendants' false claims, plus penalties prescribed by law. Relator's lawsuit is not an attack on psychiatry or psychotropic drugs. It is a whistleblower action which may tend to discourage or end specific practices by individual psychiatrists, pharmacists and foster care facilities, which violate the letter of federal law, and which corrupt the public fisc and the purposes of public policy.

Congress enacted the False Claims Act during the Civil War and repeatedly fine-tuned it, adding and clarifying the *qui tam* provisions[1], precisely to encourage lawsuits such as this. The United States Attorney General will never have sufficient resources to uncover and pursue every small instance of cheating which causes public monies not legally payable to be wasted.[2] The FCA is *the United States' primary tool* to redress fraudulent attempts to cause the government to pay out sums of money.[3] Through the FCA, encouragement of public whistleblowers can not only fill an enforcement gap, but also aid in the establishment of a culture of adherence to the letter of the law and strict management of the public fisc for officially agreed public purposes. In our current age of apparently hopeless deficits and debt passing to future generations, *qui tam* actions for false claims are all the more appropriate.

Defendants have moved for dismissal of this suit under F.R. Civ.P. 12(b)(6), detailing, in their Memorandum in Support, a complex regulatory and legal background to Medicaid reimbursement of outpatient drug prescriptions, and arguing that relator misunderstands the federal statute and cannot allege scienter. Their interpretations are incorrect.

II. ANALYSIS AND ARGUMENT

A. Scienter.

Defendants essentially argue that there is no reason they should be expected to know or acknowledge the federal law which relator alleges they violate. This position is incompatible with long established U. S. Supreme Court precedents. Justice Stevens

[1] U.S. ex rel. Lambers v. City of Green Bay, 168 F.3d 1013, at 1016-17 (7th Cir. 1999) contains a concise summary.
[2] Medicaid has "…limited ability to detect provider billing practices inconsistent with Medicaid requirements." U.S. v. Yvon Nazon, M.D., 940 F.2d 255, at 256 (7th Cir. 1991).
[3] United States' Statement of Interest in U.S. ex rel Polansky v. Pfizer, Exhibit J filed with Defendants' Memorandum in Support of their 12(B)(6) motion, Dkt. No. 39-10, p.2..

made the point in Heckler v.Community Health Services, 467 U.S. 51 at 63, 104 S.Ct. 2218, 81 L. Ed. 2d 42 (1984): "Protection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law…" and cited Justice Holmes from Rock Island, A & L. R. Co. v. United States, 254 U.S. 141 (1920): "Men must turn square corners when they deal with the government." . The defendants sought and received public funds, but they unfortunately did not act with scrupulous regard for the requirements of law or turn sufficiently square corners.

1. *Under Illinois regulations and contractual agreements, the defendants clearly agreed to know and strictly abide by federal law, as a condition of participation in the state Medicaid program.*

The Illinois Department of Healthcare and Family Services requires all prospective providers of services who may submit claims to Medicaid for payment to fill out and sign an enrollment application (Exhibit A) which includes a certification under penalties of perjury. All providers thus agree to "review and comply with the Department's policies, rules and regulations" as detailed on several websites. Prominent among the easily accessed and specifically referenced published sources, which all providers legally commit themselves to review as a condition of participation in Medicaid, is the Department's *Handbook for Providers of Medical Services* (Exhibit B).[4]

The *Handbook* is replete with references to federal as well as state laws. It repeatedly admonishes providers who participate in the Illinois Medical Assistance Program and other health care programs funded or administered by the Department

[4] The enrollment application and Handbook as attached in Exhibits A and B are acknowledged to be more recent versions than the acts of the defendants alleged in the Complaint. However, they are demonstrative on the issue of scienter as a matter of law in this case, in delineating those responsibilities which Illinois has consistently imposed (completely contrary to the Defendants' arguments in their motion) upon all enrolled Medicaid suppliers over the history of the program.

that they will be held responsible for knowing and complying with all federal and state laws, for knowing which services are covered and billing accordingly, and for making inquiries to the proper source when necessary to obtain clarification and interpretation.

If Defendants, as they each certified they would, had read or even casually perused the *Handbook for Providers of Medical Services*, they would have encountered the following first paragraph in the first chapter, "General Policy and Procedures":

> *For consideration for payment by the Department under any of its authorized programs, covered services must be provided to an eligible participant by a medical provider enrolled for participation in the Illinois Medical Assistance Program. Services provided must be in full compliance with applicable federal and state laws, Department Administrative Rules (89 Ill. Adm. Code Chapter 101), the general provisions contained in Chapter 100, General Policy and Procedures, and the policy and procedures contained in the Chapter 200 series Handbook that applies to the specific type of service or type of provider.*

Shortly following, in chapter 101.1 subtitled "Participation Requirements", Defendants should also have read that:

> *To be approved for participation, a provider must agree to … comply with the requirements of applicable federal and state laws and not engage in practices prohibited by such laws…*

Their attention would almost certainly have been drawn to chapter 136, subtitled "Fraud in the Department's Medical Programs", which states quite sternly:

> *Providers are expected to obey all laws, civil and criminal, State and federal regulations, and Department policies pertaining to delivery of and payment for health care. The Department actively monitors all claims for payments to identify suspicious activities.*
>
> *Providers suspected of fraud shall be criminally investigated and, when appropriate, prosecuted in state or federal court.*

Under such solemn contractual circumstances, defendants should have noticed if Illinois' Medicaid regulations were inconsistent with the federal statute. They were not

coerced to accept government payments under imponderably byzantine terms. As responsible professionals and business people, they should have discovered prior to or very early in their freely chosen commercial relationships with what they themselves identify as a state-federal partnership (Memorandum, page 3), that certain complexities existed which were their own legal responsibilities, not just Illinois' problem.

The defendants each accepted and certified, under penalties of perjury, an individual duty to review, clarify as necessary, and comply with *federal law* -- which of course includes 42 U.S.C. §1396r-8(k)(3) and (k)(6), defining the statutory terms, "covered outpatient drug" and "medically accepted indication". Contrary to their somewhat shrill and disingenuous protestations long after the fact, it is not "particularly preposterous to expect providers to look beyond the Illinois regulations" (Memorandum, page 11). It is, rather, a clear contractual duty at the very least, spelled out and acknowledged in a legal document which is part and parcel of the Illinois regulations. Although they knowingly contracted with a state-federal government partnership, the defendants' failed to look beyond that one particular set of regulations which they had reason to believe would most benefit their own remuneration, or to clarify and understand stricter terms to which their attention was specifically directed in writing. This failure went far beyond simple negligence to aggravated gross negligence. As a violation of defendants' contractual duty and condition of their Medicaid participation to know the requirements of the law, it was reckless disregard or deliberate ignorance.

2. *Even if the Defendants had not expressly certified their own duty to know and follow the federal Medicaid statute to the letter, they would still be charged with knowledge that their claims were false as a matter of law.*

Illinois rules and regulations do require the defendants to know and abide by federal law. However the practices and regulations of Illinois, in the Medicaid governmental partnership with the United States, cannot be a basis to independently override the definitions in federal law. Justice Frankfurter wrote in Federal Crop Insurance Corp. v. Merrill, 332 U.S. 380 at 384, 68 S.Ct. 1, 92 L.Ed. 10 (1947):

> *Whatever the form in which the Government functions, anyone entering into a arrangement with the Government takes the risk of having accurately ascertained that he who purports to act for the Government stays within the bounds of his authority.*

Illinois has no authority, merely as one partner with the United States in the Medicaid enterprise, to make, interpret or alter federal statutory definitions of "covered out-patient drug" or "medically accepted indication". This lack of authority is implicitly acknowledged in the *Handbook for Providers of Medical Services* by the repeated admonitions that all providers must know and comply with federal law. But even if it were not so acknowledged, the defendants in this case would remain at risk of having accurately ascertained the provisions of that law.

The 7th Circuit stated in Kennedy v. U.S., 965 F.2d 413 (7th Cir. 1992), that it is especially important to prevent reliance on the conduct of government agents contrary to law, because government employees could effectively "legislate" by misinterpreting or ignoring applicable statutes, and subsequent judicial validation of such unauthorized "legislation" would infringe upon Congress's exclusive constitutional authority to make law. 965 F.2d at 420. If courts allow Medicaid providers to rely upon the conduct of Illinois officials and Illinois' Medicaid regulations in contravention of the federal statute, they would likewise thereby infringe against the constitutional prerogatives of the legislative branch of the United States.

Citing Heckler, in U.S. ex rel Hagood v. Sonoma County Water Agency, 929 F. 2d 1416, 1422 (9th Cir 1991), in a False Claims Act case such as this, the Ninth Circuit Court of Appeals held that U. S. government officials' approval of a contract based on an erroneous interpretation of law did not defeat a False Claims Act cause of action, and reversed the district court's 12(b)(6) dismissal. When defendants here essentially argue that the State of Illinois ignores or misinterprets the federal statute in favor of its own policy regarding coverage of outpatient prescriptions, and that federal officials acquiesce with Illinois' Medicaid scheme, this is an admission. It does not negate scienter as a matter of law.

Because they explicitly agree to comply with Medicaid's legal requirements, all Medicaid providers, including all of the defendants here, are presumed to have knowledge of Medicaid's legal requirements. In another Ninth Circuit case, U.S. v. Mackby, 261 F.3d 821, 828 (9th Cir. 2001), the court wrote even more directly to the point of scienter:

> *Protection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law...." Heckler v. Cmty. Health Servs. of Crawford County, Inc., 467 U.S. 51, 63, 104 S.Ct. 2218, 81 L.Ed.2d 42 (1984). Participants in the Medicare program have a duty to familiarize themselves with the legal requirements for payment. Id. at 64, 104 S.Ct. 2218.*
>
> *The evidence established that Mackby was the managing director of the clinic. He was responsible for day-to-day operations, long-term planning, lease and build-out negotiations, personnel, and legal and accounting oversight. It was his obligation to be familiar with the legal requirements for obtaining reimbursement from Medicare for physical therapy services, and to ensure that the clinic was run in accordance with all laws. His claim that he did not know of the Medicare requirements does not shield him from liability. By failing to inform himself of those requirements . . . he acted in reckless disregard or in deliberate ignorance of those requirements, either of which was sufficient to charge him with knowledge of the falsity of the claims in question.*

The Seventh Circuit cited Heckler in ruling that a steel company should have known that prehearing discovery was restricted in a wrongful firing case, and that an agent of the National Labor Relations Board lacked authority to waive the restriction by promising to make a deal to engage in such discovery:

> *Moreover, the "general rule is that 'those who deal with the Government are expected to know the law and may not rely on the conduct of Government agents contrary to law.'" Kelley v. NLRB, 79 F.3d 1238, 1249 (1st Cir. 1996) (quoting Heckler v. Community Health Services, 467 U.S. 51, 63, 81 L. Ed. 2d 42, 104 S. Ct. 2218 (1984)).*"

Beta Steel Corp. v. NLRB, 2000 U.S. App. LEXIS 4112 (7th Cir. 2000) (copy attached as Exhibit C). The court ruled that, "Since Beta's counsel must know the law, his reliance on the Board agent's promises to the contrary was not reasonable." This, despite the court's own admonishment that the NLRB investigate whether its agent had actually lulled Beta's counsel with misrepresentations. FN3 at *10.

Therefore a presumption exists, that when the defendants caused or presented claims for psychiatric drugs used on children and youth that were not for a medically accepted indication, they knew such claims were false within the meaning of the False Claims Act, and the scienter requirement is satisfied as a matter of law. In order to negate this presumption, the defendants must at the very least come forward with evidence that they relied on a specific good faith interpretation *before* submitting the false claims. Relator will be entitled to discovery on the issue if such evidence is presented. No reliance upon improper allowance or facilitation of false claims by the State of Illinois can negate the presumption of defendants' knowledge that the claims were false, especially at this stage for purposes of a 12(b)(6) motion to dismiss.

Relator also believes that defendants cloud the issue of knowledge or scienter in this case by a device of conflating *false claims* with *false statements*. The U.S. Department of Justice explained in its Statement of Interest in U.S. ex rel. Polansky v. Pfizer, Case No. 04-cv-0704, Eastern District of New York (attached to defendants' Memorandum in Support as Exhibit J, Dkt. No. 39-10, p.7) that a claim for Medicaid reimbursement need not contain any deliberate and conscious lie to be a false claim under FCA:

> *The first two sections of the FCA provide independent and distinct bases for FCA liability. Compare 31 U.S.C. §3729(a)(1)(liability for false claims) with (a)(2)(liability for false statements). By its very terms, Section 3729(a)(1) only requires that the defendant presented or caused the presentment of a false4 claim, not that the defendant made a false statement or lied on the claim itself.*

The correct rule, especially in a case such as this, involving false *claims* as distinct from false *statements*, extends through the line of cases from Rock Island, A & L. R., Federal Crop Insurance and Heckler in the U.S. Supreme Court to Kennedy and Beta Steel in the Seventh Circuit. It states simply, that anyone dealing with the government is *per* se charged with knowledge of all relevant law.

B. Restriction of federal Medicaid reimbursement for outpatient drugs.

Medicaid is only permitted by Congress to reimburse states for expenditures on outpatient drugs for "medically accepted indications," defined as indications approved by the FDA or supported by a citation in any of the three compendia specified by the statute.

Defendants imply that Congress did not intend to limit Medicaid coverage of outpatient drugs as above, that claims to Medicaid for drugs prescribed by anyone licensed to prescribe can't really be false despite the §1396r-8(k)(3) limitation, and that

because §1396r-8(d)(1)(B)(i) says states may limit coverage to covered outpatient drugs, coverage must not really be limited to “covered outpatient drugs” per the federal statute’s definition. They assert that Congress may only have intended to establish "covered outpatient drugs" as a floor or minimum, not as a ceiling or maximum, that the issue has not been decided, and that the law is “forbiddingly complex” after all. This begs much interest, but it is mere diversion. The law only needs to be “forbiddingly complex” for those who must escape the consequences of violating it.

1. *The structure of §1396r-8 indicates that Congress intended Medicaid to reimburse the states only for expenditures on “covered outpatient drugs” for "medically accepted indications" as defined in subsections (k)(3) and (k)(6), respectively.*

Subsections (k)(3) and (k)(6) are located two levels above and seven subjects away from subsection (d)(1)(B)(i), within the structure of §1396r-8. For that fact of statutory structure alone, it becomes highly dubious that subsection (d)(1)(B)(i) could have been intended by Congress to directly modify or contradict subsection (k)(3). Yet the plain language of (k)(3) -- “Such term also does not include … a drug or biological [product] used for a medical indication which is not a medically accepted indication” -- leaves no room whatsoever for an interpretation consistent with defendants’ arguments.

Various provisions allow or mandate the states to restrict payment within the (k)(3) and (k)(6) defined category of "covered outpatient drugs." E.g., §1396r-8(d)(1)(A) allows states to establish prior authorization programs for covered outpatient drugs so long as they comply with §1396r-8(d)(5); §1396r-8(d)(1)(B) allows states to exclude or otherwise restrict coverage of covered outpatient drugs used for anorexia, weight loss, weight gain, cosmetic purposes or hair growth, smoking cessation, and sexual or

erectile dysfunction, or to promote fertility; §1396r-8(d)(4) allows states to establish formularies under specified rules. However, none of these provisions can be interpreted to widen or amend the plain language of basic definitions, which Congress placed at a higher level within the structure of the statute, in §1396r-8(k)(3) and (k)(6). The Defendants are simply wrong when they imply that "covered outpatient drugs" and "medically accepted indications" establish a floor or minimum, not a ceiling or maximum.

2. *The government's official position in False Claims Act cases is that Medicaid coverage for outpatient drugs is limited to "covered outpatient drugs" -- as defined in §1396r-8(k)(3) and (k)(6).*

The defendants candidly admit that the U.S. Department of Justice is not confused by any forbidding complexity in the law, but in fact officially recognizes the plain meaning of the definitions in §1396r-8(k)(3) and (k)(6). In September of 2009, the DOJ issued a news release announcing a $2.3 Billion settlement with Pfizer, stating, "[Pfizer] caused false claims to be submitted to government health care programs for uses that were not medically accepted indications and therefore not covered by those programs." (Copy attached as Exhibit D.) Similarly, the Government's February 13, 2009, Complaint in Intervention in U.S. ex rel Gobble v. Forest Laboratories, Case No. 03-cv-10395-NMG, District of Massachusetts, states that prescriptions presented to Medicaid that are not for medically accepted indications are false claims. (Copy attached as Exhibit E.) To the same effect is the settlement agreement in U.S. ex rel Wetta v. AstraZeneca Pharmaceuticals, Case No. 04-cv-3479-BMS, Eastern District of Pennsylvania. (Copy attached as Exhibit F.) Although the defendants attempt to skate around these statements in their Memorandum, they ultimately have to admit DOJ's utterly categorical recognition in 2010, in their Statement of Interest in U.S. ex rel.

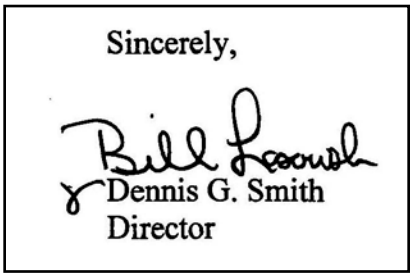
Polansky v. Pfizer (defendants' Exhibit J attached to their Memorandum, Dkt. No. 39-10):

> *…(U)nder this statutory scheme, an off-label use that is not "supported by citation" in the compendia falls outside the definition of a covered outpatient drug under Medicaid …*
>
> *Courts have held that when a drug is prescribed for a use that is not covered by federal programs, the resulting claim for reimbursement is "false" under the FCA….*
>
> *(T)he core question for "falsity" under the FCA is whether the government received a bill from a healthcare provider for an item or service that was not legally reimbursable. This is an objective question and is not, as defendant argues, a "subjective interpretation of defendant's legal duties" …*

Defendants attempt to cloud the simple reality of the government's official position by claiming that the Centers for Medicare and Medicaid Services (CMS), the federal agency which administers Medicaid, has taken the position that 42 USC §1396r-8(d)(1)(B)(i) means Congress did not limit reimbursement for covered outpatient drugs to "covered outpatient drugs" as explicitly defined under 42 USC §1396r-8(k)(3) and (k)(6). That CMS has actually taken any such position is dubious. The only support proffered for the proposition that directly addresses the issue are two letters from the Center for Medicaid and State Operations (apparently a division or department within CMS) in response to letters from the Utah Attorney General's Medicaid Fraud Control Unit. (See Exhibits C, D, E and F, Dkt. Nos. 39-3, 39-4, 39-5 and 39-6 respectively, attached to defendants' Memorandum in Support of their 12(b)(6) motion.)

This correspondence was initiated in October, 2007, by the Utah Attorney General's Office asking whether CMS interpreted the Medicaid statute as prohibiting Medicaid coverage of outpatient drugs that are not for a "medically accepted indication". After a six-week delay, a letter responding to this question in December, 2007, states,

"(the Act) does not provide definitive policy on the coverage of Medicaid drugs for the uses you describe in your letter, nor have we addressed this issue in implementing Federal regulations." The letter is signed *for* the Director of the Center for Medicaid and State Operations by someone else:



Incredulous at the response, the Utah Attorney General's Office promptly wrote back:

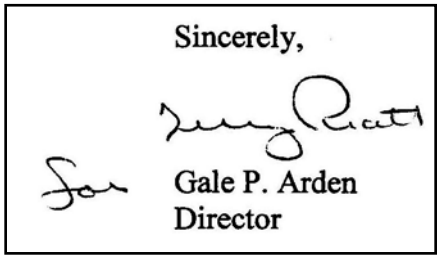
> *With all due respect, I beg to differ and direct your attention to Section 1927(k)(3) regarding a specific exception to the definition of "covered outpatient drug." In pertinent part it states that the term "covered outpatient drug" (which would otherwise be eligible for Medicaid Federal Financial Participation) does not include "a drug or biological used for a medical indication which is not a medically accepted indication."*

(Dkt. No. 39-5.) After addressing why the permissive language in 42 USC §1396r-8(d)(1)(B)(i) allowing states to restrict coverage to those that are for a medically accepted indication cannot override the specific prohibition contained in 42 U.S.C. § 1396r8(k)(3) and (k)(6), the Utah Attorney General's Office wrote:

> *I strongly encourage you to run this issue by your legal counsel and am confident that they will conclude that the clear, unambiguous definition of "covered outpatient drug" means that States are eligible for Federal Financial Participation with respect to drugs that are reimbursed only for "medically accepted indications," i.e., only for uses either approved by the FDA or "supported" in the specified compendia.*

(*Id*.)

In response, without addressing the legal issues involved and without any indication CMS was following the interpretation of its legal counsel, a letter was sent back after another six-week delay, re-affirming the previous letter. This letter is signed *for* the Director of the Center for Medicaid and State Operations, Disabled and Elderly Health Program Group (apparently a subordinate of the Director of the Center for Medicaid and State Operations over whose name the previous letter was issued):



All four persons whose names appear on these two letters from groups or subdivisions within CMS can claim they did not write the letter over their name. It is questionable whether these letters even represent the true positions of Smith and Arden, let alone the formal position of CMS. In other words, it is very dubious that these letters represent any sort of authorized interpretation of the statute by CMS. Judicial notice of these letters as a statement of position by a government agency in public records is completely inappropriate. Even were it not, defendants cite no statutory provision clearly authorizing CMS to promulgate a rule carrying the force of law to allow Medicaid to cover outpatient drug prescriptions that are not for a medically accepted indication.

The bottom line is that the defendants' supposed "disagreement over whether 42 U.S.C. § 1396r-8 acts as a limit or a floor on state Medicaid reimbursement" is an elaborately constructed product of their own wishful thinking. The text of the statute is clear from its plain language. Medicaid is *only* permitted by Congress to reimburse

states for expenditures on "covered outpatient drugs" for "medically accepted indications," as defined in 42 U.S.C. § 1396r-8(k)(3) and (k)(6).

Anyone requesting or causing a request that Medicaid reimburse expenditures for prescriptions which do not meet these restrictions makes a false claim under the FCA.

Defendants cloud the issue of Medicaid reimbursement for outpatient drugs by one additional device in their Memorandum. They erroneously state (page 1, third paragraph) that this "suit attacks Medicaid reimbursement for psychotropic drugs prescribed 'off label'" – and then frequently repeat this term, "off label". But off label prescriptions are not the same thing under applicable law as prescriptions *not for a medically accepted indication*. Off label prescriptions *are* reimbursable under Medicaid, *if they are for a medically accepted indication*.[5] The suit only attacks Medicaid reimbursement for drugs which are not covered outpatient drugs.

Relator is aware that the defendants here are not pharmaceutical manufacturers and presumably not involved in the complex drug approval and labeling procedures of the FDA. Dr. Spigelman may legally prescribe any drug according to her best clinical judgment, and Sears Pharmacy may legally fill that prescription for Hephzibah, whose employee brings it to them. The designation of "off label" primarily relates to pharmaceutical marketing. It is not so relevant to the legal issues in this case, namely *false claims* presented to Medicaid by Sears, caused by Spigelman's prescriptions, which Hephzibah requested and then administered. The key terms here are "covered outpatient drugs" and "medically accepted indication". Spigelman's prescriptions of

[5] These distinctions are also concisely discussed in the United States' Statement of Interest in U.S. ex rel. Polansky v. Pfizer. (See defendants' Exhibit J attached to their Memorandum, Dkt. No. 39-10, p. 2-4.) Note that Polansky involved FCA claims related to off-label *marketing* by a pharmaceutical manufacturer.

Celexa for relator's child were off label, but that is of no matter. The point is, the prescriptions were to a Medicaid recipient not for a medically accepted indication, so the resulting Medicaid claims were not for a covered outpatient drug and therefore false claims under FCA.

III. CONCLUSION

The Complaint adequately states a claim for violation of the FCA. It should not be dismissed with prejudice under F.R.Civ.P. 12(b)(6). Defendants' motion should be denied.

Respectfully submitted,

/s/ S. Randolph Kretchmar
Attorney for Relator
ARDC Reg. # 6275303

S. RANDOLPH KRETCHMAR
ATTORNEY AT LAW
1170 MICHIGAN AVENUE
WILMETTE, IL 60091
(847) 853-8106 voice
(847) 853-0114 fax
(847) 370-5410 mobile
srandolphk@gmail.com

State of Illinois
Department of Healthcare and Family Services

PROVIDER ENROLLMENT APPLICATION
ILLINOIS MEDICAL ASSISTANCE PROGRAM

(Must be Typed or Printed Legible and Do Not Use Highlighter On Any Documents.)
All fields must be completed or the application may be returned. If a field is Non-Applicable, the applicant should type or print NONE.

SECTION A: PROVIDER

1. New Enrollment ☐ Re-Enrollment ☐ Name Change ☐ Reinstatement Request ☐ 2. Provider Type
3. Provider Name
4. Primary Office Address
5. City 6. County
7. State 8. Zip Code 9. Telephone: 10. Fax:
11. E-mail Address (3)
12. National Provider Identification # - NPI **Report Additional NPI's In Section D** 13. FEIN
14. SSN 15. License/Certification 16. DEA
17. Medicare Part A# 18. Organization Type 19. Control of Facility 20. Fiscal Year
21. CLIA #

SECTION B: SERVICE/SPECIALTY

22. Category of Service
23. Provider Specialty: Primary Specialty Secondary Specialties
24. Physician UPIN No. 25. OBRA Qualifications (Physicians Only)
26. Hospital Admitting Privilege: (Physicians Only)

Hospital Name Address

Hospital Name Address

27. Pharmacy Location 28. Pharmacist In Charge 29. License #
30. Electronic Billing? Yes ☐ No ☐ 31. If Yes, Pharmacy Software Vendor Name 32. Pharmacy NCPDP#
33. Transportation: Taxi Base/Meter/Flag Rate 34. Taxi Mileage Rate 35. Medicar: Hydraulic Manual Lift or Ramp Yes ☐ No ☐
36. Long Term Care Medical Bed Capacity 37. Long Term Care Medicare Fiscal Intermediary
38. Long Term Care Building ID Code

SECTION C: FORMER PARTICIPATION

39. Change of Ownership Yes ☐ No ☐ Effective Date

40. Former Provider Number Former Provider Name

SECTION D: ADDITIONAL NPI - National Provider Identification #

41. NPI NPI NPI

NPI NPI NPI

SECTION E: PAYEE INFORMATION

42. Name 43. Telephone:

44. DBA

45. Street Address

46. City 47. State 48. Zip Code 49. TIN Type Code

50. SSN/FEIN 51. Billing Provider/Pay To NPI #

52. Medicare Part B# 53. PIN 54. DMERC#

Name Telephone:

DBA

Street Address

City State Zip Code TIN Type Code

SSN/FEIN Billing Provider/Pay To NPI #

Medicare Part B# PIN DMERC#

SECTION F: CERTIFICATION/SIGNATURE

I understand that knowingly falsifying or willfully withholding information may be cause for the denial or termination of participation in the Medical Assistance Program and such conduct may be prosecuted under applicable Federal and State laws..

Under penalties of perjury, I hereby certify that all of the information provided in this application process is true, correct and complete and that the enrolling provider is in compliance with all applicable federal and state laws and regulations. I further certify that neither I, nor any of the following provider's employees, partners, officers, or shareholders owning at least five percent (5%) of said provider are currently barred, suspended, terminated, voluntarily withdrawn as part of a settlement agreement, or otherwise excluded from participation in the Medicaid or Medicare programs, nor are any of the above currently under sanction for, or serving a sentence for conviction of any Medicaid or Medicare program violations. I further certify that none of the above are currently sanctioned by any federal agency for any reason. I authorize the Department of Healthcare and Family Services, to verify the information provided on this application with other state and federal agencies. I further certify that I will review and comply with the Department's policies, rules and regulations including but not limited to those found at the following websites:

Illinois HFS website address: http://www.hfs.illinois.gov/
Illinois HFS Handbook updates are available: http://www.hfs.illinois.gov/handbooks
Illinois HFS Laws and Rule Regulations: http://www.hfs.illinois.gov/lawsrules/index.html

Check this box if you want a provider handbook mailed ☐

Signature: Date

Printed name of person signing above

Handbook for Providers of Medical Services

Chapter 100
General Policy and Procedures

Illinois Department of Healthcare and Family Service

CHAPTER 100
GENERAL POLICY AND PROCEDURES

TABLE OF CONTENTS

GENERAL APPENDICES

FOREWORD

PURPOSE

Handbooks have been prepared for the information and guidance of providers who participate in the Illinois Medical Assistance Program and other health care programs funded or administered by HFS. Handbooks state HFS policy with sufficient instructions and guidelines to enable providers to:

- know which services provided to eligible participants are covered;
- submit proper billings for services rendered; and
- make inquiries to the proper source when it is necessary to obtain clarification and interpretation of Department policy and coverage.

Providers will be held responsible for compliance with all policy and procedures contained herein.

FORMAT

A complete handbook consists of two sections:

Chapter 100 contains general policy, procedures and appendices applicable to all participating providers.

Chapter 200 contains specific policy, procedures and appendices applicable to the provision of a specific type or category of service.

A separate Chapter 200 is published for each type of provider or category of service. Each is designated by an alphabetical character. HFS will reissue all Chapter 200 series Handbooks to conform with changes made in this release of Chapter 100. As each is reissued, all providers enrolled for that specific type of service will be notified via a hard copy Provider Notice. Each Handbook will be made available for downloading from the Department's Web site <http://www.hfs.illinois.gov/handbooks/>. Hard copies will be available upon request. Requests for Handbooks should be directed to the Provider Participation Unit (PPU). Refer to Topic 101 for the address of the PPU.

The organization and alphabetical numbering system of the reissued Handbooks will be as follows:

Handbook Number	Type of Provider or Service
N-200	Advanced Practice Nurse
G-200	Ambulatory Surgical Treatment Center
E-200	Audiology
B-200	Chiropractor
	Dentist
M-200	Durable Medical Equipment
D-200	Encounter Rate Clinics
R-200	Home Health
K-200	Hospice
H-200	Hospital
X-200	Imaging Center (currently called Portable X-ray)
L-200	Laboratory
C-200	Long Term Care
O-200	Optometrist, Optician, Optical Company
P-200	Pharmacy
A-200	Physician
F-200	Podiatrist
S-200	School Based Clinics
W-200	Supportive Living Facility
J-200	Therapy (Physical, Occupational and Speech)
T-200	Transportation

Depending on the range of services, a provider may need more than one Handbook from the Chapter 200 series.

Within the Handbooks, Topics are arranged similarly. For example, if any services covered in any handbook are subject to prior approval, the prior approval process will be explained in Topic 211.

Note: The Handbook for Dental Providers is produced and distributed by the Department's dental contractor, Doral Dental of Illinois. Copies of that Handbook, which is titled the Dental Office Reference manual, may be requested by calling Doral Dental Provider Relations at 1-888-281-2076.

MAINTENANCE OF HANDBOOK

The pages of the Handbook are prepared for insertion in a three-ring binder for ease in use. Revisions and supplements to the Handbooks will be released from time to time as operating experience and State or federal laws require policy and procedure changes. Updates and changes to each Handbook will also be published on the Department's Web site at http://www.hfs.illinois.gov/

Transmittals of revisions and supplements will be consecutively numbered. It is suggested that providers record receipt of all transmittals and subsequent updating of their copies of Handbooks. It is very important that all appropriate billing staff be provided with copies of all handbook updates.

DEPARTMENT WEB SITE

The Department maintains an Internet Web site at http://www.hfs.illinois.gov/ Providers are encouraged to browse the Web site to determine which information is important to them.

Chapter 100 of the Provider Handbook is available on the Internet. The Web site address is http://www.hfs.illinois.gov/handbooks/

Updates to Chapter 100 will be posted on the Web site as Provider Bulletins at http://www.hfs.illinois.gov/releases/

As each Handbook in the Chapter 200 series is updated and released, it will also be made available on the Department's Web site.

The Department also posts many other items of interest on the Web site, including Administrative Rules and other pertinent government Web site addresses.

ADDRESSES AND TELEPHONE NUMBERS

Bureau of Comprehensive Health Services	**Phone: 1-877-782-5565**
• Physicians, Chiropractors, Podiatrists, Independent Laboratories, X-ray	P.O. Box 19115 Springfield, Illinois 62794-9115 Fax 217-524-7120
• FQHC, Rural Health Clinic (RHC), Encounter Rate Clinic (ERC), Transportation, Advanced Practice Nurse	P.O. Box 19116 Springfield, Illinois 62794-9116 Fax: 217-524-7120
• Dental, Optometric	201 South Grand Ave. East Springfield, Illinois 62763-0001 Fax: 217-524-7120
• Prior Approval – Pharmacy	P.O. Box 19117 Springfield, Illinois 62794-9117 Fax: 217-524-7264
• Durable Medical Equipment, Audiology Home Health Services, Speech, Occupational and Physical Therapy	P.O. Box 19126 Springfield, Illinois 62794-9126 Fax: 217-524-7120
• Prior Approval – Medical Equipment, Home Health Services, Therapies	P.O. Box 19124 Springfield, Illinois 62794-9124 Fax: 217-524-7194
• UB-92 Claims for Inpatient Hospital, Outpatient Hospital, Renal Dialysis, Ambulatory surgical Treatment Centers	P.O. Box 19128 Springfield, Illinois 62794-9128 Fax: 217-524-4283
• Hospice	P.O. Box 19110 Springfield, Illinois 62794-9110 Fax: 217-524-4283
Provider Participation Unit	**Phone: 217-782-0538** Fax: 217-557-8800
• Enrollment and Handbooks	P.O. Box 19114 Springfield, Illinois 62794-9114

Bureau of Contract Management	**Phone: 217-524-7478** Fax: 217-524-7535
• Marketing • Contract Monitoring and Administration	201 South Grand Ave. East Springfield, Illinois 62763
Fraud and Abuse Hotline	**Phone: 1-800-252-8903**
Bureau of Long Term Care	**Phone: 217-782-0545** Fax: 217-524-7114
• Supportive Living Facilities • Nursing Facilities	201 South Grand Avenue East Springfield, Illinois 62763
Third Party Liability	**Phone: 217-524-2490** Fax: 217-557-1174
• Insurance Coverage Changes	P.O. Box 19120 Springfield, Illinois 62794-9120
AVRS Provider Health Care Hotline • Eligibility Information	**Phone: 1-800-842-1461** Available 24 hours/day
Department of Human Services (DHS) Helpline	**Phone: 1-800-843-6154** **Fax: 217-524-0083**
Office of Health Finance	**Phone: 217-782-1630** Fax: 217-782-2812
• Hospital Cost Reports • Long Term Care Facility Cost Reports	201 South Grand Avenue East Springfield, Illinois 62763
Bureau of Medicaid Integrity	**Phone: 217-782-2121** Fax: 217-782-1745
• Audits of Medical Providers	404 North 5th Street Springfield, Illinois 62702

ACRONYMS AND ABBREVIATIONS

AABD – Aid to the Aged, Blind and Disabled

AABD MANG – Aid to the Aged, Blind and Disabled receiving Medical Assistance only

AVRS – Automated Voice Response System

CMS – Centers for Medicare and Medicaid Services

CPT – Current Procedural Terminology, a nationally standardized system for coding procedures and services performed by practitioners

DCFS – Department of Children and Family Services

DEPARTMENT – Department of Healthcare and Family Services

DHS – Department of Human Services

DHS ORS – Department of Human Services/Office of Rehabilitation Services

DOC – Department of Corrections

DPA – Department of Public Aid

DPH – Department of Public Health

DSCC – Division of Specialized Care for Children

ECC – Electronic Claims Capture

ECP – Electronic Claims Processing

EFT – Electronic Funds Transfer

EPSDT – Early and Periodic Screening, Diagnosis and Treatment

ERC – Encounter Rate Clinic

FCRC – Family Community Resource Center

FQHC – Federally Qualified Health Center

HCPCS – Healthcare Common Procedure Coding System, a nationally standardized system for coding services and supplies

HFS – Healthcare and Family Services

HIPAA – Health Insurance Portability and Accountability Act

HMO – Health Maintenance Organization

ICD-9-CM – International Classification of Diseases, 9th Edition, Clinical Modification, a nationally standardized system for coding diagnoses and procedures

MCCN – Managed Care Community Network

MCO – Managed Care Organization

MEDI – Medical Electronic Data Interchange

NCPDP – National Council of Prescription Drug Program

NDC – National Drug Code, a nationally standardized system for coding pharmaceuticals and certain medical supplies

NIPS – Non-Institutional Provider Services

NNSF or NSF – New National Standard Format

PCP – Primary Care Physician or Primary Care Pharmacy

QMB – Qualified Medicare Beneficiary

RHC – Rural Health Clinic

REV – Recipient Eligibility Verification System

RRP – Recipient Restriction Program

TANF – Temporary Assistance to Needy Families

TPL – Third Party Liability

CHAPTER 100

GENERAL POLICY AND PROCEDURES

100 HFS MEDICAL PROGRAMS – BASIC PROVISIONS, AUTHORITY AND OBJECTIVE

For consideration for payment by the Department under any of its authorized programs, covered services must be provided to an eligible participant by a medical provider enrolled for participation in the Illinois Medical Assistance Program. Services provided must be in full compliance with applicable federal and state laws, Department Administrative Rules (89 Ill. Adm. Code Chapter 101), the general provisions contained in Chapter 100, General Policy and Procedures, and the policy and procedures contained in the Chapter 200 series Handbook that applies to the specific type of service or type of provider.

The objective of the Department's Medical Programs is to enable eligible participants to obtain necessary medical care. "Necessary medical care" is that which is generally recognized as standard medical care required because of disease, infirmity or impairment. Preventive care is covered in certain circumstances, as specified in Topic 103 and in the Chapter 200 Series Handbooks.

Payment for necessary medical care and certain preventive services, as specified in Chapter 100, Topic 103, is made to participating providers when it is not available without charge or is not covered by health insurance or other liable third parties. As specified by rule, prior approval requirements may be imposed for some services.

Both fiscal considerations and good administrative practice require the imposition of certain limitations and controls on the kind and amount of medical care covered by the Department's Medical Programs. Careful review of the Handbook material will enable providers to identify specific program coverages and limitations.

Programs under which the Department is authorized to make payments include the following.

100.1 MEDICAL ASSISTANCE PROGRAM

The Illinois Medical Assistance Program is the program which implements Title XIX of the Social Security Act (Medicaid). It is administered by HFS under the Illinois Public Aid code. The Department has statutory responsibility and authority for the formulation of medical policy in conformance with federal and State requirements.

100.2 ALL KIDS PROGRAM

All Kids, a joint federal and state funded program, operates under Title XIX and XXI of the Social Security Act, the Illinois Public Aid Code [305 ILCS 5/1-1 et seq.] and the Children's Health Insurance Program Act [215 ILCS 106] that authorize HFS to administer an insurance program to assist families in providing or purchasing health insurance benefits for their children. Through All Kids, the Department provides health benefits coverage to eligible families, children and pregnant women by providing health care benefits or by subsidizing the cost of private health insurance, including employer health insurance.

Four All Kids plans are encompassed by this Handbook:

- All Kids Assist Plan – This plan pays for a child's health care with no copayments or premiums from the participant.
- All Kids Share Plan – This plan pays for a child's health care with a low copayment due from the participant on certain services. Refer to Topic 114.
- All Kids Premium Plan – This plan requires participants to pay a low premium each month and a low copayment on certain services. Refer to Topic 114.
- Moms & Babies – This plan covers pregnant women throughout pregnancy, 60 days postpartum and babies for the first year of the baby's life with no copayments or premiums from the participant.

100.3 TRANSITIONAL ASSISTANCE PROGRAM (CITY OF CHICAGO) AND STATE FAMILY AND CHILDREN ASSISTANCE PROGRAM (CITY OF CHICAGO)

Medical coverage for participants in the Transitional Assistance Program and the Family and Children Assistance Program is administered by HFS under Article VI of the Illinois Public Aid Code (305 ILCS 5/6-1 et seq).

The Department has statutory responsibility and authority for the formulation of medical policy in conformance with state requirements. Both programs are funded by the state, with no federal participation.

100.4 QMB PROGRAM

The Department's Qualified Medicare Beneficiary (QMB) Program assists persons who are eligible for Medicare with the costs of Medicare cost-sharing, i.e. premiums, deductibles and coinsurance. QMB/Medicaid participants are enrolled in Medical Assistance as well as Medicare. QMB Only participants are eligible only for

payment of Medicare cost sharing. The only items considered for payment for QMB Only participants are the deductibles and coinsurance on services which are covered by Medicare.

100.5 STATE RENAL DIALYSIS PROGRAM

The State Renal Dialysis Program is operated by the Department under the authority of the Renal Disease Treatment Act (410 ILCS 430). This program covers the cost of renal dialysis services for eligible Illinois residents diagnosed with chronic renal failure.

100.6 STATE HEMOPHILIA PROGRAM

The State Hemophilia Program is operated by the Department under the authority of the Hemophilia Care Act (410 ILCS 420). This program provides assistance to eligible patients for antihemophilic factors, annual comprehensive visits and other outpatient medical expenses related to the disease.

100.7 STATE SEXUAL ASSAULT SURVIVORS EMERGENCY TREATMENT PROGRAM

The Illinois Sexual Assault Survivors Emergency Treatment Program is administered under the authority of the Sexual Assault Survivors Emergency Treatment Act (410 ILCS 70). This program provides payment for medical expenses for sexual assault survivors who seek emergency services from a certified hospital and who are not eligible for Medical Assistance or All Kids nor are covered for these services by a policy of health insurance. It is not necessary for the assault to be proven in order for services to be covered.

For hospital certification to participate in the Sexual Assault Survivors Emergency Treatment Program, contact:

Illinois Department of Public Health
Office of Health Care Regulations
525 W. Jefferson, 5th floor
Springfield, IL 62761
Telephone: 217-782-2913

100.8 HEALTH BENEFITS FOR PERSONS WITH BREAST OR CERVICAL CANCER

The Department implemented Health Benefits for Persons with Breast or Cervical Cancer effective August 1, 2001. The program was expanded effective September 1, 2006 under the Treatment Act Expansion. This program assists uninsured persons who have been found to have breast or cervical cancer or a precancerous condition.

100.9 HEALTH BENEFITS FOR WORKERS WITH DISABILITIES (HBWD)

The Department implemented Health Benefits for Workers with Disabilities effective December 1, 2001. This program assists persons with disabilities who wish to go to work, or to increase their earnings without the fear of losing Medicaid benefits.

101 PROVIDER PARTICIPATION

To receive payment for medical care, services and supplies provided to individuals eligible for any of the HFS Medical Programs, a provider must enroll and be approved for participation by HFS.

To enroll for participation, providers shall:

- Hold a valid, appropriate license where state law requires licensure of medical practitioners, agencies, institutions and other medical vendors;
- Be certified for participation in the title XVIII Medicare program where federal or state rules and regulations require such certification for the Title XIX Medicaid participation;
- Be certified for Title XIX Medicaid when federal or state rules and regulations so require;
- Provide enrollment information to the Department in the prescribed format (see Topic 201 in the chapter 200 series), and notify the Department in writing promptly whenever there is a change in any such information which the provider has previously submitted;
- Provide disclosure, as requested by the Department, of all financial, beneficial, ownership, equity, surety, or other interests in any and all firms, corporations, partnerships, associations, business enterprises, joint ventures, agencies, institutions or other legal entities providing any form of health care service to eligible participants;
- Have a written provider agreement on file with the Department.

PROVIDER ENROLLMENT PROCEDURE

To participate in the HFS Medical Programs, providers must complete a Provider Enrollment Application. To obtain an enrollment application, contact the Provider Participation Unit. Requests may be made by mail, e-mail or phone at:

Illinois Department of Healthcare and Family Services
Provider Participation Unit
Post Office Box 19114
Springfield, Illinois 62794-9114

Telephone: 217-782-0538
Fax: 217-557-8800
E-Mail: hfs.PPU@illinois.gov
Web site: http://www.hfs.illinois.gov/enrollment/

The Department will confirm that enrollment has been completed by sending a Provider Information sheet to the provider. Further information on this process for each type of provider is described in Topic 201 in the Chapter 200 series.

101.1 PARTICIPATION REQUIREMENTS

To be approved for participation, a provider must agree to:

- verify eligibility of the patient prior to providing each service (not applicable where prohibited by law, for example, emergency ambulance services or hospital emergency room services);
- allow all patients the choice of accepting or rejecting medical or surgical care or treatment;
- inform patients prior to providing a noncovered service for which the patient will be held financially liable, that payment for such service cannot be made by the Department;
- provide supplies and services in full compliance with all applicable provisions of state and federal laws and regulations pertaining to nondiscrimination and equal employment opportunity, including, but not limited to:
  - full compliance with title VI of the Civil Rights Act of 1964, which prohibits discrimination on the basis of race, color or national origin;
  - full compliance with section 504 of the Rehabilitation Act of 1973 and Part 84 of title 45 of the code of Federal Regulations, which prohibit discrimination on the basis of handicap; and
  - without discrimination on the basis of religious belief, political affiliation, sex, age or disability;
- comply with the requirements of applicable federal and state laws and not engage in practices prohibited by such laws;
- hold confidential, and use for authorized program purposes only, all Medical Assistance information regarding patients;
- furnish to the Department, in the format and manner requested by it, any information it requests regarding payments for providing goods or services or supplies to patients by the provider, his or her agent, employer or employee;
- provide services and supplies to patients in the same quality and mode of delivery as are provided to the general public, and charge the Department in amounts not to exceed the provider's usual and customary charges;
- accept as payment in full the amounts established by the Department, except in limited instances involving allowable spenddown or co-payments, as described in Topics 113 and 114:
  - if a provider accepts an individual eligible for medical assistance from the Department as a Medicaid recipient, such provider must not bill, demand, or otherwise seek reimbursement from that individual or from a financially responsible relative or representative of the individual for any service for which reimbursement would have been available from the Department if the provider had timely and properly billed the Department. For purposes of this subsection, "accepts" shall be deemed to include:
    - an affirmative representation to an individual that payment for services will be sought from the Department;

- an individual presents the provider with his or her medical card and the provider does not indicate that other payment arrangements will be necessary; or
- billing the Department for the covered medical service provided an eligible individual.

- If an eligible individual is entitled to medical assistance with respect to a service for which a third party is liable for payment, the provider furnishing the service may not seek to collect from the individual payment for that service if the total liability of the third party for that service is at least equal to the amount payable for that service by the Department;

- accept assignment of Medicare benefits for participants eligible for Medicare, when payment for services to such persons is sought from the Department;
- in the case of long term care providers, assume liability for repayment to the Department of any overpayment made to the facility regardless of whether the overpayment was incurred by a current owner or operator or by a previous owner or operator.

These requirements are further detailed in 89 Illinois Administrative Code 140, Subpart B and in relevant Topics throughout the provider handbooks.

101.2 TERMINATION OF PROVIDER PARTICIPATION

A participating provider may terminate participation in the Department's Medical Programs at any time, unless the provider has a contractual relationship with the Department which provides otherwise.

Exception: In the case of long term care providers, facilities must give written notice at least 60 days prior to the date of termination. For a complete description of these requirements, refer to the Handbook for Long Term Care Facilities.

Written notification of voluntary termination is to be sent to:

Illinois Department of Healthcare and Family Services
Provider Participation Unit
Post Office Box 19114
Springfield, Illinois 62794-9114

The Department may terminate or suspend a provider agreement or a provider's eligibility to participate in the Department's Medical Programs pursuant to administrative proceedings. Department rules concerning the bases for such terminations or suspensions are set out in 89 Illinois Administrative Code 140.16. Department rules concerning administrative proceedings involving terminations or suspensions of medical vendors are set out in 89 Illinois Administrative Code 104, Subpart C.

The occurrence of a termination, either voluntary or involuntary, does not preclude the recovery of identified overpayments.

102 PATIENT ELIGIBLITY

Payment can be made by the Department only for covered medical care and services provided to individuals who are eligible on the date services are actually provided. It is the responsibility of the provider to verify a patient's eligibility prior to providing services, except where prohibited by law, for example, emergency ambulance services or hospital emergency room services.

This Topic provides a brief overview of eligibility determination processes. Topic 108.4 explains how information on the eligibility card can be used to determine which agency and office is responsible for eligibility issues on a particular patient.

102.1 MEDICAL ASSISTANCE PROGRAM

Under an interagency agreement with HFS, the Department of Human Services (DHS) takes applications and determines the eligibility of individuals and families for the Medical Assistance Program. HFS' All Kids unit can determine eligibility for children, pregnant women, parents and caretaker relatives who apply by means of a mail-in or Web application. The Department of Children and Family Services (DCFS) is responsible for children who are covered by Medicaid and who are wards of the Sate or whose care is subsidized by DCFS. All persons covered under the Medical Assistance program are issued a monthly MediPlan Card (Form HFS 469) by DHS and HFS assumes responsibility for the processing and payment of medical services.

Evidence of eligibility is demonstrated by any of the following:

- Form HFS 469, MediPlan Card (see Topic 108.1)
- Form HFS 1411CF, Temporary MediPlan Card (see Topic 109)
- Form HFS 1411, Temporary MediPlan Card (see Topic 109)
- Form HFS 469D, Temporary MediPlan Card (see Topic 109)

102.2 ALL KIDS PROGRAM

Eligibility for this program is determined by the Department's central All Kids Unit or, through an interagency agreement, by the Department of Human Services (DHS).

Evidence of eligibility for All Kids Assist and Moms and Babies is demonstrated by any of the following medical cards:

- Form HFS 469, MediPlan Card (see Topic 108.1)
- Form HFS 1411CF, Temporary MediPlan Card (see Topic 109)
- Form HFS 1411, Temporary MediPlan Card (see Topic 109)

Evidence of eligibility for All Kids Share and All Kids Premium is demonstrated by the following medical card:

- Form HFS 469KC, All Kids Identification Card (see Topic 108.2)

102.3 TRANSITIONAL ASSISTANCE PROGRAM (CITY OF CHICAGO) AND STATE FAMILY AND CHILDREN ASSISTANCE PROGRAM (CITY OF CHICAGO)

Under an interagency agreement with HFS, the Department of Human Services (DHS) processes applications and determines the eligibility of individuals and families for both programs.

Evidence of eligibility is demonstrated by any of the following:

- Form HFS 469, MediPlan Card (see Topic 108.1)
- Form HFS 1411CF, Temporary MediPlan Card (see Topic 109)
- Form HFS 1411, Temporary MediPlan Card (see Topic 109)

102.4 QMB PROGRAM

Under an interagency agreement with HFS, the Department of Human Services (DHS) processes applications and determines the eligibility of individuals and families for Medicare cost-sharing under the QMB Program.

Evidence of eligibility is demonstrated by any of the following:

- Form HFS 469, MediPlan Card (see Topic 108.1)
- Form HFS 1411CF, Temporary MediPlan Card (see Topic 109)
- Form HFS 1411, Temporary MediPlan Card (see Topic 109)

102.5 STATE RENAL DIALYSIS PROGRAM

The application package is supplied by the Department to social workers in renal dialysis centers. The social workers assist the patient in completing the application and submit it to the Department. Department staff perform a financial and eligibility evaluation and determine what the patient's participation fee, if any, will be.

No eligibility card is issued. Questions regarding applications or the eligibility of participants in the Renal Dialysis Program should be directed to the Bureau of Comprehensive Health Services at 1-877-782-5565.

102.6 STATE HEMOPHILIA PROGRAM

Eligibility for this program is determined by the Department. Department staff conduct a financial evaluations and determine what the patient's participation fee, if any, will be. Once they are approved for coverage, participants are sent an application every fiscal year to reapply.

Applications are returned to

Department of Healthcare and Family Services
Attn: Hemophilia Program
P. O. Box 19129
Springfield, Illinois 62794-9129

No eligibility card is issued. Questions regarding applications or the eligibility of participants in the State Hemophilia Program should be directed to the Bureau of Comprehensive Health Services at 1-877-782-5565.

102.7 STATE SEXUAL ASSAULT SURVIVORS EMERGENCY TREATMENT PROGRAM

The Illinois Sexual Assault Survivors Emergency Treatment Program covers medical expenses for sexual assault survivors who seek emergency services from a certified hospital and who are not eligible for Medical Assistance or All Kids nor are covered for these services by a policy of health insurance.

Another resource for these patients is

Office of the Attorney General of Illinois
Crime Victims Compensation Program
100 W. Randolph St., 13th Floor
Chicago, Illinois 60601
Telephone (312) 814-2581

Other inquiries on this program should be directed to the Bureau of Comprehensive Health Services at 1-877-782-5565.

102.8 HEALTH BENEFITS FOR PERSONS WITH BREAST OR CERVICAL CANCER

Eligibility for this program is determined by the Department's Breast and Cervical Cancer (BCC) Eligibility Unit.

Evidence of eligibility for the Breast and Cervical Cancer Program is demonstrated by any of the following medical cards:

- Form HFS 469, MediPlan Card (see Topic 108.1)
- Form HFS 1411CF, Temporary MediPlan Card (see Topic 109)
- Form HFS 1411, Temporary MediPlan Card (see Topic 109)

Questioning regarding the Breast and Cervical Cancer Program should be directed to the Department of Public Health Helpline at 1-888-522-1282.

102.9 HEALTH BENEFITS FOR WORKERS WITH DISABILITIES (HBWD)

Eligibility for this program is determined by the Department's Health Benefits for Worker with Disabilities (HBWD) unit in Springfield.

Evidence of eligibility for the Health Benefits for Workers with Disabilities Plan is demonstrated by any of the following:

- Form HFS 469, MediPlan Card (see Topic 108.1)
- Form HFS 1411CF, Temporary MediPlan Card (see Topic 109)
- Form HFS 1411, Temporary MediPlan Card (see Topic 109)

Applications are returned to:

Health Benefits for Workers with Disabilities
P.O. Box 19145
Springfield, Illinois 62794-9145

Questioning regarding the Health Benefits for Workers with Disabilities should be directed to 1-800-226-0768.

102.10 STATE AGENCY CONTACTS

Unless otherwise noted above, the contact procedures for inquiries to the State agencies responsible for determining eligibility are described below.

DHS Family Community Resource Center (FCRC) are organized and supervised by regions. When providers need to make contact with DHS regarding a participant, the FCRC that serves the county in which the participant lives is to be contacted. In Cook County, providers should contact the appropriate neighborhood FCRC.

The Department of Children and Family Services (DCFS) has responsibility for administering its own cases. Eligibility for DCFS cases is determined by DHS staff located within the DCFS facility. When providers need to make contact with DCFS regarding a participant, the DCFS Regional Medical Liaison that serves the county in which the child is living is to be contacted.

Inquiries to HFS regarding eligibility for any medical program may be directed to 1-800-842-1461.

102.1 PRIOR AND RETROACTIVE COVERAGE

Once their coverage begins, participants in the Medical Assistance and All Kids programs receive monthly medical cards that document their eligibility and coverage limitations. See Topic 108 for examples and an explanation of the contents of the monthly MediPlan and All Kids Cards.

When they initially apply for coverage, Medical Assistance, All Kids Assist and Moms and Babies applicants may request that their coverage be backdated to cover services they may have received for up to three months prior to month of their application. The first time children are approved for All Kids Share or All Kids Premium Level 1, the children may be eligible for payment of medical services received from two weeks before the date of application until the date All Kids coverage begins.

If a participant's request for retroactive coverage is granted, it is sometimes documented by a Temporary Identification Card. Examples and an explanation of Temporary Identification Cards can be found in Topic 109. Prior coverage may also be documented by a letter from the Department's central All Kids unit.

Retroactive coverage for Medical Assistance and All Kids Program participants is not always documented by a Temporary Identification Card or letter. If the participant cannot produce such documentation, but requests that a provider bill the Department for medical services or items provided during the retroactive or prior coverage period, the provider may verify eligibility via the Recipient Eligibility Verification system (see Topic 131.2), the Department's toll-free AVRS Provider Health Care Hotline (1-800-842-1461), or by contacting the responsible administrative office as described in Topic 102.10.

103 COVERED SERVICES

The range of services for which the Department will pay varies depending on the program or plan under which a participant is covered.

Topic 108 provides facsimiles of the MediPlan and All Kids Cards and describes how to determine which persons are eligible for each of the following lists of services, using the Case ID Category numbers and eligibility restriction messages contained on the Card.

103.1 MEDICAL ASSISTANCE AND ALL KIDS PROGRAMS

The medical services that are covered for participants in Medical Assistance (Medicaid), All Kids Assist and Moms and Babies include the following.

- Physician services
- Hospital Inpatient Services
- Hospital Emergency Room Visits
- Hospital Ambulatory Services
- Ambulatory Surgical Treatment Center Services
- Encounter Rate Clinic Visits
- Pharmacy Services
- Laboratory/X-ray Services
- Optical Services/supplies
- Chiropractic Services
- Hospice Services
- Optometrist Services
- Advanced Practice Nurse Services
- Audiology Services
- Dental Services
- Family Planning Services and Supplies
- Podiatric Services
- Transportation to secure medical services
- Long Term Care Services
- Home Health Agency Visits
- Physical, Occupational and Speech Therapy Services
- Renal Dialysis Services
- Medical Supplies, Equipment, Prostheses and Orthoses
- Respiratory Equipment and Supplies

In addition to the services listed above, certain medical services that are funded through other state agencies are covered for participants in Medical Assistance (Medicaid), All Kids Assist and Moms and Babies. These include:

- Services provided through a waiver approved under Section 1915(c) of the Social Security Act (funded through the Department on Aging and DHS),

- Mental health services provided under the Medicaid Clinic Option or Medicaid Rehabilitation Option (funded through DHS and DCFS), and
- Subacute alcohol and substance abuse treatment services (funded through DHS).

Note: Individuals participating in Medical Assistance, All Kids Assist and Moms and Babies receive a MediPlan Card. See Topic 108.1.

The medical services that are covered for participants in All Kids Share and All Kids Premium Level 1 are the same as those listed above, with the following exceptions:

- those services provided through a waiver approved under Section 1915(c) of the Social Security Act, and
- abortion services.

Note: Individuals participating in All Kids Share and All Kids Premium receive an All Kids Card see Topic 108.2.

103.2 STATE TRANSITIONAL ASSISTANCE PROGRAM (CITY OF CHICAGO ONLY)

The following medical services are covered for participants in the Transitional Assistance Program:

- Physician services
- Laboratory/X-ray Services
- Vital Pharmacy Services and vital Medical Supplies, Equipment, Prosthetic Devices and Respiratory Equipment. ("Vital" means those items or services that are necessary for life maintenance or to avoid life-threatening situations.)
- Transportation to secure medical services
- Dental Services
- Optical Services and Supplies
- Chiropractic Services
- Podiatric Services
- Hospice Services
- Long Term Care Services (subject to prior approval)
- Home Health Agency Services
- Encounter Rate Clinic Visits
- Family Planning Services and Supplies

Note: Hospital services of any type are not covered for participants of the Transitional Assistance Program. This limitation on coverage also applies for any other service if it is billed by the hospital.

103.3 STATE FAMILY AND CHILDREN ASSISTANCE PROGRAM (CITY OF CHICAGO ONLY)

The following medical services are covered for adult participants in the State Family and Children Assistance Program:

- Physical Services
- Vital Pharmacy Services and vital medical Supplies, Equipment, Prosthetic Devices and Respiratory Equipment. ("Vital" means those items or services that are necessary for life maintenance or to avoid life-threatening situations.)
- Hospital Inpatient Services and Hospital Ambulatory Services (and all ancillaries) for surgical procedures, renal dialysis, cancer therapy or follow-up burn treatment. (Note Physical rehabilitation services and psychiatric services are not covered.)
- Hospital Emergency Room visits
- Transportation to secure medical services
- Laboratory/X-ray Services
- Dental Services
- Optical Services and Supplies
- Chiropractic Services
- Podiatric Services
- Hospice Services
- Long Term Care Services (subject to prior approval)
- Home Health Agency Services
- Encounter Rate Clinic Visits
- Family Planning Services and Supplies

Children in the State Family and Children Assistance Program are covered for the full range of services described in Topic 103.1, without exception.

103.4 EMERGENCY SERVICES DEFINED

Throughout all the programs administered by the Department, the following definition of "emergency services" is used, unless otherwise specified:

The words "emergency services" mean those services which are for a medical condition manifesting itself by acute symptoms of sufficient severity (including, but not limited to, severe pain) such that a prudent lay person, possessing an average knowledge of medicine and health, could reasonably expect that the absence of immediate attention would result in placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or their unborn child) in serous jeopardy, serous impairment to bodily functions, or serious dysfunction of any bodily organ or part.

103.5 STATE RENAL DIALYSIS PROGRAM

The only medical service covered for participants in the State Renal Dialysis Program is the dialysis itself.

103.6 STATE HEMOPHILIA PROGRAM

Medical services covered for participants in the State Hemophilia Program vary according to the age of the participant.

For children under the age of 21, the Department reimburses for blood clotting factor only. Other medical expenses are reimbursed by the University of Illinois at Chicago, Division of Specialized Care for Children (DSCC).

For adults, the Department reimburses for blood clotting factor and other medical expenses related to the disease, including:

- Two comprehensive exams per year
- Hospital Outpatient Services
- Hospital Emergency Room Visits
- Physician Services
- Laboratory Services
- Blood Transfusion
- Medical Supplies

The above services are covered only when they are directly related to the participant's hemophilia.

103.7 STATE SEXUAL ASSAULT SURVIVORS EMERGENCY TREATMENT PROGRAM

The following medical services are covered for participants in the State Sexual Assault Survivors Emergency Treatment Program:

- Physician Services
- Hospital Emergency Room Visits
- Transportation to the Hospital Emergency Room
- Drugs and Medical Supplies
- Follow-up services such as physician, laboratory and pharmacy, for a period of 90 days

The above services are covered only when they are directly related to an alleged sexual assault. The Department will allow the provider to use their judgment to determine whether the services being provided are related to the sexual assault.

103.8 HEALTH BENEFITS FOR PERSON WITH BREAST OR CERVICAL CANCER

Participants in the Breast and Cervical Cancer Program receive the same medical benefits as the participants in the Medical Assistance Program. Refer to Topic 103.1

103.9 HEALTH BENEFITS FOR WORKERS WITH DISABILITIES (HBWD)

Participants in the Health Benefits for Workers with Disabilities Program receive the same medical benefits as the participants in the Medical Assistance Program. Refer to Topic 103.1.

104 SERVICES NOT COVERED

Services and supplies for which payment will not be made under any of the Department's Medical Programs include, but are not limited to, the following:

- Services available without charge
- Services prohibited by state or federal law
- Experimental procedures
- Research oriented procedure
- Medical examinations required for entrance in to adult educational or vocational program
- Autopsy examinations
- Routine (well-person) examinations
- Artificial insemination
- Abortion except in accordance with the provisions of 89 Ill. Admin Code 140.413(a)(1)
- Medical or surgical procedures performed for cosmetic purposes
- Medical or surgical transsexual treatment services
- Diagnostic or therapeutic procedures related to secondary infertility/sterility
- Acupuncture
- Subsequent treatment for venereal disease, when such services are available free of charge through state and/or local health agencies
- Medical care provided by mail or telephone, except for approved Telemedicine services described in Chapter 200 (Note: this does not prohibit the mailing of medically necessary covered item, for example, prescription drugs sent to a patient by a mail-order pharmacy.)
- Unkept appointments
- Services provided by terminated or barred providers
- Preparation of routine records, forms and reports
- Visits with persons other than a patient, such as family members or long term care facility staff.
- Items or services for which medical necessity is not clearly established
- Services provided only, or primarily, for the convenience of patients or their families
- Services or supplies not personally rendered by the billing provider, unless specifically allowed in this handbook or in the Chapter 200 series or otherwise specifically authorized in writing by the Department.

Deceased people are not eligible for services, even though the Department's eligibility files may still temporarily show that they are active, covered participant's. Payments for services rendered after the death of a participant will be recovered by the Department. Other action may be taken as appropriate, including possible civil or criminal fraud prosecution where warranted.

Chapter 200 may contain other exclusions, which are specific to a provider type or category of service.

105 MANAGED CARE ORGANIZATIONS (MCO)

Some participants have prepared health services, contracted for by the Department, through voluntary enrollment in a Managed Care Organization (MCO). A Managed Care Organization (MCO) may be a Health Maintenance Organization (HMO) or a Managed Care Community Network (MCCN).

An MCO is responsible for providing or arranging and making reimbursement for all covered Medical Assistance services, with the exception of dental services, optical services (vision refractions and corrective lenses) and under certain circumstances, family planning services. An MCO is responsible for only limited long term care facility services.

Participants enrolled in MCOs will receive medical cards with the following message:

MANAGED CARE ENROLLEE(S): Services may require payment authorization.

Before providing services to any participant with a MANAGED CARE ENROLLEE card, the provider should be sure of the arrangements for reimbursement. In no instance will the Department reimburse a provider when the services is one for which the MCO is contractually responsible.

Included as covered are the following services and benefits which will be provided to participants by their MCO whenever medically necessary.

- Inpatient Hospital Services (including hospitalization for acute medical detoxification and dental hospitalization in case of trauma or when related to a medical condition)
- Inpatient Psychiatric Care
- Outpatient Hospital Services
- Laboratory and X-ray Services
- Nursing Facility (Long Term Care) Services for the first 90 days
- Physicians Services, including psychiatric care
- Home Health Agency Services
- Clinic Services
- Pharmacy Services (including drugs prescribed by a dentist participating in the Department's Medical Programs), provided they are filled by an MCO network pharmacy
- Physical, Occupational and Speech Therapies.
- Transportation to secure medical services
- Family Planning Services
- Services required to treat a condition diagnosed as a result of Healthy Kids (EPSDT) services
- Blood, blood components, and the administration thereof
- Podiatric services
- Durable and nondurable Medical Equipment and Supplies

- Chiropractic Services
- Emergency Services
- Routine care in conjunction with certain investigational cancer treatments
- Audiology Services
- Assistive/augmentative Communication Devices
- Behavioral Health Services, including subacute alcohol and substance abuse services and mental health services
- Hospice Services
- Medical procedures performed by a dentist
- Nurse Midwife services
- Orthotic/prosthetic devices, including prosthetic devices or reconstructive surgery incidental to a mastectomy
- Transplants
- Diagnosis and treatment of medical conditions of the eye (may be provided by an optometrist operating within the scope of his or her license)
- Services to prevent illness and promote health

The Department will pay participating providers directly covered services that are not included in an MCO's contract. In the case of dental services, Doral Dental of Illinois, the Department's dental administrator, will make payment.

Family planning services are the contractual responsibility of the MCO when a covered service is provide by any provider in the MCO's network. Participants enrolled in an MCO can obtain family planning services out-of-network from any enrolled provider. Family planning services performed by an out-of-network provider may be billed directly to the Department.

106 RECIPEINT RESTRICTION PROGRAM (RRP)

The Department identifies participants who overuse medical services. When the Department determines that a Medical Assistance or All Kids participant has received medical or pharmacy services in excess of need or in such a manner as to constitute an abuse of the program, the Department restricts the participant to a Primary Care Physician (PCP) or Primary Care Pharmacy or both, or to a Managed Care Organization (MCO).

When a participant is restricted, the participant will be notified in writing and given the opportunity to select a Primary Care Physician or Pharmacy or both, or to select an MCO. In the event that a participant does not select a Primary Care Physician or Pharmacy or both or an MCO, a Primary Care Physician or Pharmacy or both will be designated by the Department for the participant.

If a participant has been restricted, the MediPlan or All Kids Card will contain notice of this restriction and show the name of the Primary Care Physician or Pharmacy or both or the MCO. In the event that a Temporary Card is issued, the card will contain a message of pending restriction.

The PCP and pharmacy restriction messages are as follows:

- The primary physician named below must provide or authorize the following services on a non-emergent basis: physician, pharmaceutical, clinical, outpatient hospital, laboratory and podiatric, if applicable.
- The primary pharmacy named below must supply or authorize all drugs.

A combination of both messages will appear if the individuals is restricted to both a Primary Care Physician and Primary Care Pharmacy.

The MCO restriction message is as follows:
MANAGED CARE ENROLLEE: Services may require payment authorization

Providers who have questions about a participant's RRP status or whether a given service to a restricted participant requires authorization may call the Department's toll-free RRP hotline at 1-800-325-8823.

The Department will not pay for restricted services that are provided on a nonemergency basis without prior written authorization of the designated Primary Care Physician or Pharmacy. This authorization will be on the completed Form HFS 1662, Primary Care Physician Referral Authorization, originated by the Primary Care Physician or Pharmacy.

106.1 MEDICAL SERVICES RESTRICTED BY RRP

The following medical services may only be provided to restricted participants when authorized by the Primary Care Physician or Pharmacy via Form HFS 1662, Primary Care Provider Referral Authorization or when the PCP or Primary Care Pharmacy is the billing provider.

When such designation is made, all physician, drug, clinic, laboratory and podiatric services provided to the participant on a nonemergent basis must be provided or authorized by the Primary Care Physician or Pharmacy, as appropriate. Emergency services, as defined in Topic 103.4, may be provided without prior authorization from the PCP or Primary Care Pharmacy.

The Department will not pay for the following services if they are provided on a nonemergency basis unless prior written authorization (Form HFS 1662) has been received from the Primary Care Physician or Primary Care Pharmacy designated on the restricted participant's MediPlan Card or Temporary Card. When the following services are provided on an emergency basis, authorization (Form HFS 1662) must be obtained from the PCP after service is performed.

- Physicians
- Outpatients Hospital – Scheduled or Elective Procedures
- Laboratory Services
- Outpatient Hospital Services
- Encounter Rate Clinics – FQHCs, RHCs, and ERCs
- Independent Laboratories – Form HFS 1662 is not required if the referring practitioner is PCP
- Pharmacy – Form HFS 1662 is not required if the prescribing practitioner is the PCP
- Podiatric Services
- Outpatient Hospital Clinic

See Topic 112.6 for instructions on billing restricted services.

106.2 MEDICAL SERVICES NOT RESTRICTED BY RRP

The following medical services are not affected by the Recipient Restriction Program and do not require Form HFS 1662, Primary Care Physician Referral Authorization.

- Dental Care – provided through the Department's Dental Contractor
- Hospital Services – Inpatient and Emergency Services
- ESRD Renal Dialysis Services
- Home Health Care
- Hospice Services
- Chiropractic Services
- Medical Equipment

- Optical/Optician Services
- Long Term Care Services
- Transportation Services

106.3 RRP RESTRICTION IN AN MCO

When a participant is restricted and chooses to enroll in an MCO, that participant is subject to the MCO's policies regarding services, which do or do not require the authorization of PCP. Refer to Topic 105.

108 IDENTIFICATION CARDS

MediPlan and All Kids are issued monthly. Some children served by DCFS are issued cards on an annual basis. A family may receive more than one card per month in instances where the number of persons in the case or the length and number of messages on the card are greater than the space available for printing. If medical coverage is restricted in any way, a printed message will appear on the card.

Participants in the State Renal Dialysis Program, the State Sexual Assault Survivors Emergency Treatment Program and the State Hemophilia Program do not receive identification cards. Participants in All Kids Rebate do not receive a card from the Department, but may have an identification card from the employer-sponsored or private health insurance plan under which they are covered.

Spenddown participants receive MediPlan cards only for periods when their spenddown has been met and they are actually eligible for Department payment for their medical expenses. Refer to Topic 113 for a more complete explanation of spenddown.

Temporary cards are explained in Topic 109.

108.1 MEDIPLAN CARD

Form HFS 469, MediPlan Card, is the identification card issued on a monthly basis by the Department to each person or family who is eligible under Medical Assistance, Transitional Assistance (City of Chicago), State Family and Children Assistance (City of Chicago), All Kids Assist or Moms and Babies.

In addition, the MediPlan card may be issued for a Qualified Medicare Beneficiary (QMB) who is not eligible for Medical Assistance, but is eligible for Department consideration for payment of Medicare coinsurance and deductibles. In these instances, the MediPlan Card is clearly marked “QMB Only”.

MediPlan cards are printed on white paper with the State of Illinois seal printed in light blue.

108.2 ALL KIDS IDENTIFICATION CARD

Form HFS 469KC, All Kids Identification Card, is the identification card issued on a monthly basis by the Department to each person or family who is eligible under All Kids Share or All Kids Premium. All Kids cards are printed on canary yellow paper with the All Kids logo printed at the top.

108.3 IDENTIFICATION VERIFICATION

An individual who claims to be an eligible participant, but is unable to present a current and valid card, should be considered ineligible until proven otherwise. See Topic 113 for an explanation of the eligibility status of enrolled spenddown participants.

To assure proper identification of eligibility for a person who presents an identification card issued by the Department, either the MediPlan Card or All Kids Card, the provider should:

- Ask for some additional piece of identification to ensure that the person presenting the card is actually the same person listed on the card.
- Determine that the date of service is within the period eligibility printed on the card.
- Ensure that the card presented is a valid card. All valid MediPlan Cards are computer printed with the State of Illinois seal shown on the front in light blue. All valid All Kids Identification Cards are computer printed on yellow stock with the All Kids logo shown at the top. (See Topic 108.4 and Topic 108.5 for examples of the front and back of each card and messages they carry).

Cards that are questionable and that should be investigated include:

- Cards that have been altered in any manner;
- Cards containing any handwritten entries;
- MediPlan Cards without a State Seal or MediPlan Cards with a State Seal in any color other than light blue;
- All Kids Identification Cards that do not contain co-payment information;
- All Kids Identification Cards that do not have the All kids logo shown at the top;
- All Kids Identification Cards on other than yellow stock; or
- Cards that do not follow the format of the sample cards described in this Topic.

The identification card should be considered valid only if the participant is able to produce the complete card at the time services are rendered.

Providers may contact the FCRC for further verifications of questionable MediPlan Cards. Providers may verify a participant's eligibility via AVRS by calling the Provider Health Care Hotline 1-800-842-1461. Providers may contact the regional DCFS office for verification of eligibility of children served by DCFS. Providers may contact the Department's Central All Kids Unit for further verification of questionable (yellow) All Kids Cards.

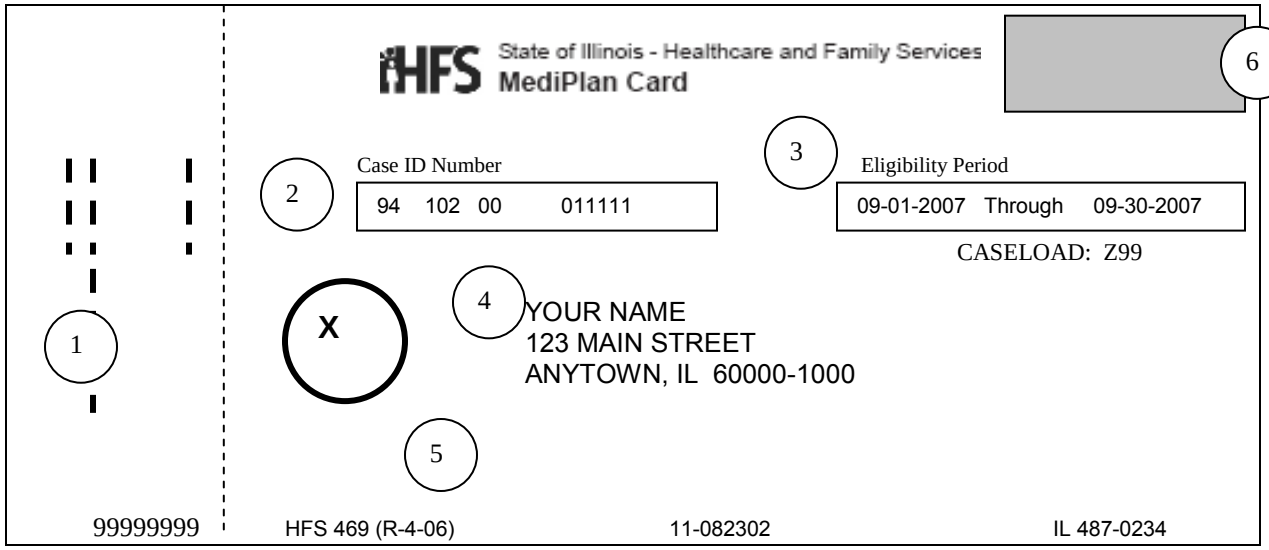
Providers may also utilize the REV system for verification of either Medical Assistance of All Kids eligibility, restrictions or co-payments. See Topic 131.2 for an explanation of the REV system.

If a provider suspects fraud or abuse regarding the use of a MediPlan or All Kids Card, the provider should call the Fraud and Abuse Hotline, at 1-800-252-8903.

108.4 PRIMARY PORTION (FRONT) OF IDENTIFICATION CARDS

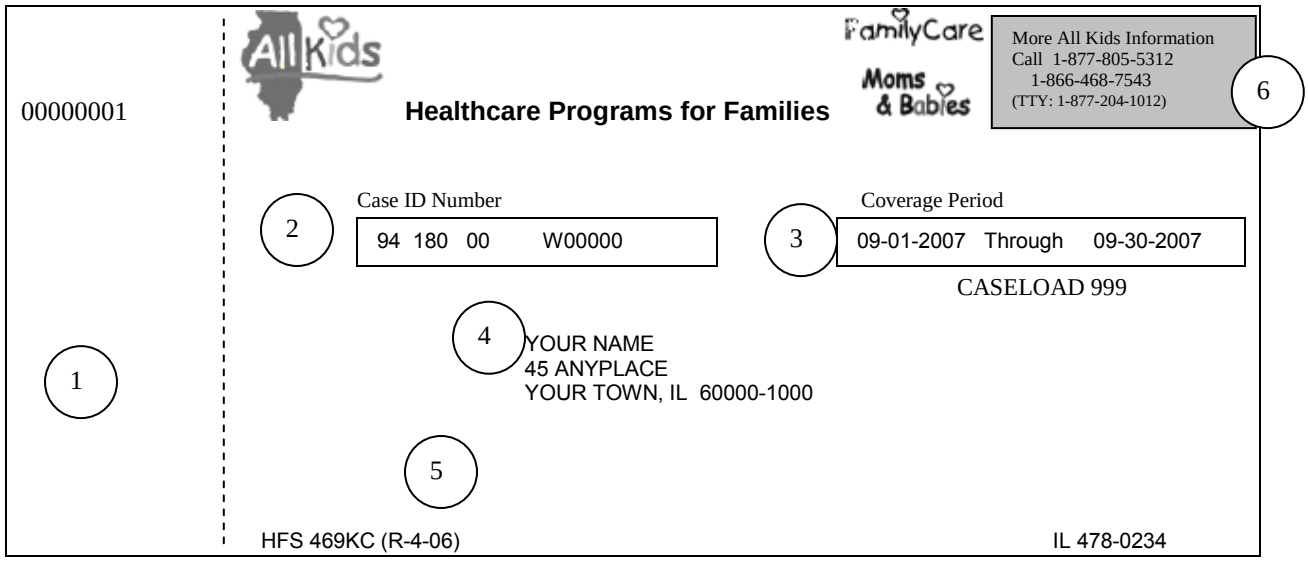
Reduced facsimiles of the primary portion (front) of the MediPlan Card and All Kids Card are provided on the next page. An explanation of the contents of the front portion of both cards is provided on the following pages. The item numbers that correspond to the explanations appear in small circles, for example (5)

Reduced facsimile of the primary portion (front) of the MediPlan Card



Note: The seal of the state of Illinois appears in blue ink in the spot marked with a large X in a circle.

Reduced facsimile of the primary portion (front) of the AllKids Card



Note: the All Kids Card is printed on canary yellow paper.

FIELD OR ITEM	EXPLANATION
(1) **Control Area**	This area is for state use only. It is separated from the remainder of the card by a thin broken line. On the MediPlan Card, the small control number that appears near the top of the card in this section is repeated on the back of the card. This area also contains a series of vertical lines, which may vary from card to card. The large control number near the bottom appears only on the front of the card.
(2) **Case ID Number**	The case identification number identifies the specific case or family unit in which all participants listed on the card are included. The case identification number may be used by the provider as a reference when contacting the Department, the FCRC or the regional DCFS office. This number is not to be used by the provider on billing documents. The number is composed of four distinct elements, each of which has a specific meaning: **Category -** The first two digits indicate the program or category to which the participant belongs. Persons in the following categories are eligible to receive covered services as listed in Topic 103.1. 00 90 98 01 91 02 92 P2 03 93 P3 04 94 P4 06 96 P6 **Exception**: For a small number of persons in categories 91, 92 and 93, the MediPlan Card may have a designation of "QMB Only". Service coverage for such persons is limited. For an explanation of this message, see the field titled "Program Coverage" in Topic 108.5. Children who are wards of the Department of Children and Family Services (DCFS) or the Department of Corrections (DOC) are assigned case identification numbers beginning with **category 98.**

Persons eligible for the Transitional Assistance Program or the State Family and Children Assistance Program in the City of Chicago are assigned case identification numbers beginning with **category 07.** They are eligible to receive only the services listed in Topics 103.2 and 103.3. The only exception is that children 18 years of age or younger in these cases in the City of Chicago are eligible to receive the full scope of covered services as listed in Topic 103.1.

FCRC - The second set of digits identifies the office by which the participant's coverage is maintained.

DHS FCRCs outside Cook County are assigned numerical codes ranging from 010 through 115. Three downstate counties - Kane, Madison and St. Clair - are divided into districts and have more than one number assigned. Cook County is also divided into districts with each district office assigned a number in the 200 series.

FCRC codes 180 through 189, 196 and 220 indicate that the participant's case is managed directly by HFS' central unit.

FCRC codes 211, 313, 611, 612, 613, 711 and 713 indicate that the participant's case is managed by DCFS. Also see the exception described under the Group Number heading below.

Group Number - The third set of digits is used by the state to schedule administrative activities. It has no significance to providers. (**Exception**: Group 30, when shown after FCRC code 211, identifies cases managed by DOC.)

Basic Number -- The fourth and last set of digits, known as the basic number, identifies the specific case. Within each county, a unique basic number is assigned to each case. The basic number ranges from 6 to 8 digits and may contain both alphabetic characters and numerals.

3 **Eligibility/ Coverage Period**

The dates listed in this section are the inclusive beginning and end dates of the coverage period documented by the card. Coverage for periods before or after the dates on the card can be verified following the instructions in Topic 108.3.

4 **Case Name and Address**

The case name appears in conjunction with the mailing address. It is the main identifier associated with the case identification number. The individual whose name appears as the case name is not eligible for medical services unless the name also is shown in the listing of "eligible persons" on

the back of the card. In instances in which a second individual, a bank, an agency or an institution has been designated as guardian, protective payee or representative payee, the applicable name and identifying initials will appear as part of the mailing address.

5 **Messages** A variety of explanatory messages may appear in this area. They include such subjects as allowable co-payments and managed care restrictions. Further information on the meaning and impact of each message can be found elsewhere in this handbook, in the Topic devoted to the subject of the message.

6 **Special Limitations** If there is a program coverage designation in the upper right shaded (black) area of the MediPlan Card, it will by "QMB ONLY".

No other program coverages or coverage limitations are shown in the upper right area on the front of the MediPlan Card. Other limitations (if any) appear either below the name and address in the **Messages** area or on the back of the card immediately below the name of each eligible person.

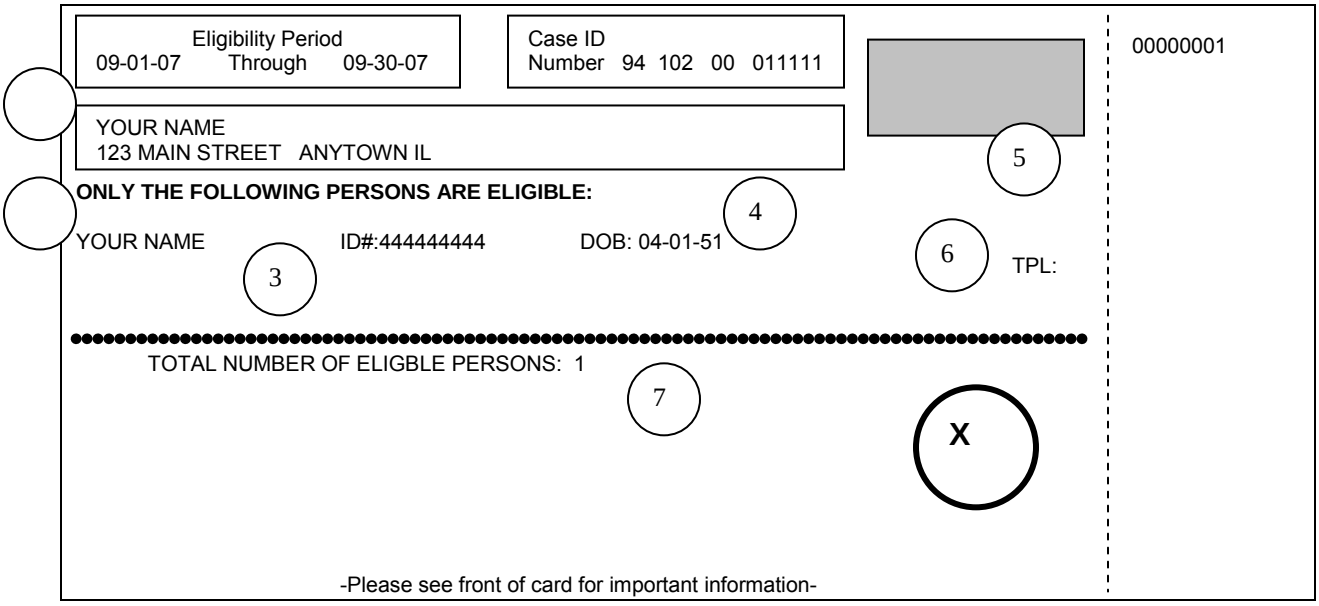
All Kids Cards do not have coverage designations in the upper right area of the card.

On some but not all cards, a bar code appears immediately above the shaded area.

108.5 ELIGIBLE PERSONS PORTION (BACK) OF IDENTIFICATION CARDS

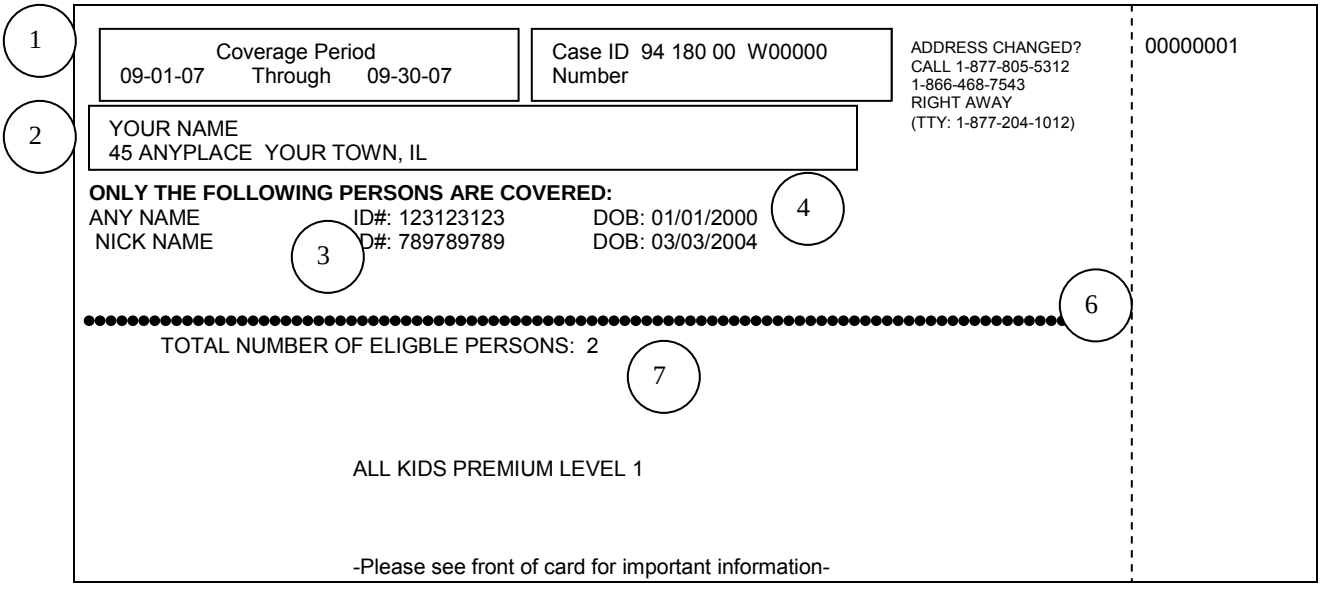
Reduced facsimiles of the eligible persons portion (back) of the MediPlan Card and All Kids Card are provided on the next page. An explanation of the contents of the back of both cards is provided on the following pages. The item numbers that correspond to the explanations appear in small circles, for example 6

Reduced facsimile of the eligible persons portion (back) of the MediPlan Card



Note: The seal of the State of Illinois appears in blue ink in the spot marked with a large X in a circle.

Reduced facsimile of the covered persons portion (back) of the All Kids Card



FIELD OR ITEM	EXPLANATION
(1) **Items Repeated from the Front of the Card**	The Eligibility/Coverage Period, Case ID Number and Case Name and Address that appear on the front of the card also appear in the three boxes on the back of the card. These items are explained in Topic 108.4. Also, if a message appears in the shaded box on the front of the MediPlan card, that same message appears in the shaded area on the back.
(2) **Name and Program Coverage Messages**	The first column in this area shows the name of every covered participant in the case. The order of the name is first name, middle initial and last name. The name, exactly as shown on the card, of the person to whom services were rendered should be entered as the patient name on the provider's claim. On the MediPlan card, a Program Coverage Message will be shown immediately below the name of each covered person. One or more of the following program coverage messages will appear as appropriate to the individual: **GENERAL ASSISTANCE** - specific program limitations are applicable and are specified on the card. **GA - NO HOSPITAL** - this is a category 07 case and hospital services are not covered. **QMB ONLY** - the individual listed is eligible for coverage as Qualified Medicare Beneficiary (QMB), but is not eligible for Illinois Medical Assistance. The Department considers for payment only the deductible and coinsurance amounts on Medicare covered services. (This notation will also appear in the upper right shaded area on the front of the card.) **QMB/MEDICAID** - the individual is eligible to receive the full scope of covered services listed in Topic 103.1. This message indicates that the person is also eligible for coverage as a Qualified Medicare Beneficiary (QMB); therefore, Medicare is to be billed for covered services prior to billing the Department. **MEDICAID** - the individual is eligible to receive the full scope of covered services listed in Topic 103.1. If any restrictions to this are applicable, they are specified in the message area of the card. **PRENATAL NO INPATIENT** - the individual is participating in the Illinois Medical Assistance Presumptive Eligibility

Program (MPE) and is covered for ambulatory prenatal care only. No inpatient or long term care services are authorized.

MANAGED CARE - the individual is assigned to a specific MCO. The name and telephone number of the MCO will be shown to the right of this message. When there is such a designation, no other medical provider is to provide non-emergency services, other than dental, optical and family planning services, without first contacting the MCO.

On the All Kids card, if a participant is enrolled in a managed care plan, the **Managed Care** message will appear immediately below the name of that participant. If no one in the family is enrolled in managed care, the name of each covered person is the only information that appears in this column.

3 **Recipient Identification Number (RIN)**

To the right of each covered person's name is the unique, nine-digit Recipient Identification Number for that individual. Each number is valid for only one person. Because this identification number is used to verify eligibility, it is essential that the provider take extreme care when entering the number on the billing form. Use of incorrect numbers is a common cause of billing rejections.

It is imperative that the specific number for the patient to whom the medical service was rendered, be used on HFS billing forms and on Medicare billing forms if they are expected to electronically cross over to HFS.

4 **Date of Birth**

The individual's complete birth date appears in the next column. Its form is month (two digits), day (two digits) and year (two digits).

5 **Medicare Coverage**

The next column to the right identifies Medicare coverage of the individual. An entry will appear in this column only if the participant has Medicare coverage. If the space in this column is blank, it indicates that neither DHS or HFS is aware of Medicare eligibility. This does not eliminate the provider's responsibility to inquire about such coverage. The codes which may appear in this column are listed below with the type of coverage:

CODE	TYPE OF COVERAGE
PART A	HOSPITAL INSURANCE
PART B	HOSPITAL INSURANCE
PART AB	BOTH OF THE ABOVE

6 **TPL**

The last column of each line will identify, by code, known third party resources. Information entered here will refer to the Department's record of such resources. The TPL resource code will consist of a three-digit numeric code that may be prefixed with an alphabetic coverage code. The three-digit resource code identifies a specific health insurance company or union fund. The alpha coverage code, if present, indicates the extent of coverage provided by the resource.

EXAMPLE: A participant who is insured under a health plan by Aetna Life Insurance Company will have "001" printed in the TPL column of the MediPlan card. The addition of the prefix "A" (A001) will indicate the participant has a "comprehensive" health plan underwritten by Aetna.

For an explanation of the TPL codes which may appear on the MediPlan Card, refer to General Appendix 9, Third Party Liability Resource Codes.

The lack of a code in this space means that the Department is not aware of any TPL coverage. It does not eliminate the provider's responsibility to inquire about the possibility of such coverage.

7 **Total Persons**

The total number of persons listed in this line should always match the number of individual participants listed above the line.

109 TEMPORARY IDENTIFICATION CARDS

A Temporary MediPlan or All Kids Card is valid for the covered medical services as listed in Topics 103.1, 103.2 or 103.3, depending on the category code in the Case ID Number. If specific information is applicable for an individual case or person, it will be reflected on the card.

Form HFS 1411, Temporary MediPlan Card, is issued by the FCRC or the central HFS office to participants who are in need of immediate medical services prior to the receipt of their MediPlan or All Kids Card. It is a multi-part light blue form, with red pre-printed control numbers on the front and an explanation of the contents of the form printed on the back. There are two versions of the form, which are identical except that one has the DHS logo and name at the top, and the other has the HFS logo and name at the top.

Form HFS 1411CF, Temporary MediPlan Card, is a computer generated temporary card but it is the same as Form HFS 1411 in its usage as it pertains to a medical provider. Form 1411CF is printed on 81/2" x 11" sheets of plain white paper. Please note that, for a Form 1411CF to be valid, it must contain an FCRC or HFS office embossed seal.

Form HFS 469D, Temporary MediPlan Card, is issued by the local office of the Department of Children and Family Services (DCFS) to wards who are in need of immediate medical services prior to the receipt of their MediPlan Card. It is the last page of a multipart form printed on paper with a distinctive blue pattern. It does not have an embossed seal.

Form HFS 469D may not contain the Recipient Identification Number (RIN). A DCFS toll free number (1-800-228-6533) is available which providers can access during normal business hours to obtain the RIN for billing purposes. The toll free number is also printed on the reverse side of the temporary card.

Temporary Cards can be valid for up to thirty days. Each card should be carefully viewed to be sure that services provided are within the eligibility period shown. If the date on which the service is rendered does not fall within this time period, the provider should follow the procedures described in Topic 100 to determine if eligibility existed on the date of service.

If a service is provided to a participant who presents Form HFS 1411CF or 469D the provider should photocopy the form to use, if needed, to rebill a rejected claim. If a service is provided to a participant who presents Form HFS 1411, the provider should detach one copy to use, if needed, to rebill a rejected claim. The appendices of Chapter 200 contain billing instructions when a Temporary Card is used to verify eligibility.

On the following pages are reduced facsimiles of the front and back of Form HFS 1411. The version that is shown contains the HFS logo and name. The DHS version of the form is identical except on the front, the Department of Human

Services logo and name appear on the top of the form. The back of Form HFS 1411 is identical, regardless of which Department's logo appears on the front.

Also shown are reduced facsimiles of Form HFS 1411CF and Form HFS 469D.

Illinois Department of Healthcare and Family Services

MEDICAL PROVIDERS AND CLIENTS
SEE REVERSE SIDE

TEMPORARY MEDIPLAN CARD

DATE ISSUED

SPLIT BILL DAY

ELIGIBILITY PERIOD FOR TEMPORARY MEDIPLAN CARD

ALL BILLS ON SPLIT BILL DAY REQUIRE FORM HFS 2432

CAT.	LOCAL OFFICE	GRP.	BASIC

RESTRICTION CODES_____
DATE_____

CLIENT_____
RESTR. CODE/TYPE_____
PRIM. PROVIDER_____

_____
_____
_____

HFS 1411 (R-3-95) IL478-0297

ONLY THE FOLLOWING PERSON ARE EIGIBLE **9990099**

CLIENT FIRST	CLIENT LAST	RECIPIENT NUMBER	BIRTHDATE MM/DD/YY	RD	CM	MEDICARE CODE	TPL CODE

TOTAL NUMBER OF ELIGIBLE PERSONS_____

9990099

REGULAR DOCTOR (RD) NAME AND PHONE NUMBER
1.
2.
3.
4.

CASE MANAGER (CM) NAME AND PHONE NUMBER
1.
2.
3.
4.

Reduced Facsimile of Back of Form HFS 1411

THIS CARD IS NOT VALID IF IT HAS BEEN ALTERED OR CHANGED IN ANY MANNER

NOTICE OF CLIENT – This card is not transferable. Use by person other than those named is illegal.

NOTICE OF DHS STAFF – All items are to be completed if applicable to the case. If not applicable, enter XXXX.

NOTICE TO MEDICAL PROVIDERS – Not all types of medical goods and services are covered by public assistance programs. If in doubt whether specific goods or services are authorized for person(s) listed, contact the appropriate central office of the Department of Healthcare and Family Services as indicated in your Medical Assistance Program Handbook. You should require adequate identification from the person(s) using this card to obtain medical goods or services.

The following information provided for each eligible person listed on the front of this card: full name, recipient number, birthdate, Medicare coverage and TPL indicators Part A and /or B indicators refer to Medicare coverage (view the Medicare Health insurance Card to verify coverage and correct claim number). TPL indicators identify other known sources available for payment of Medicare expenses. Bill Medicare and TPL source **before** you bill the Department of Healthcare and Family Services. NOTE: Split Bill Day refers to the date the spend-down obligation was met.

Check the front of this card to see if persons are restricted to one or more of the following: limited services, a managed care program, a primary physician and/or a primary pharmacy.

INFORMATION/RESTRICTION MESSAGES

1. Emergency services are permitted.
2. All bills on split bill day ***MM-DD-YY require Form HFS 2432
3. Persons age 17 and under are eligible for AFDC (04) medical coverage
4. Identification only. This card is not good for any type of medical services
5. Limited to GA (Category 07) Covered Services
6. GA (Category 07) services only. Hospital services are not covered.
7. Managed care enrollee(s). Services may require payment authorization
8. The primary physician named on the card must provide or authorize the following services to the client named below on a non-emergent basis: physician, clinical, pharmaceutical, outpatient hospital, laboratory and podiatric. The primary pharmacy named on the card must provide or authorize all prescription drugs on a non-emergent basis.
   Dr. John Smith
   The Pill Box Pharmacy
9. The primary physician named on the card must provide or authorize the following services on a non-emergent basis: physician, pharmaceutical, clinical, outpatient hospital, laboratory and podiatric.
   Dr. John Smith
10. The primary pharmacy named on the card must supply or authorize all prescription drugs.
    The Pill Box Pharmacy
11. The primary physician named on the card must provide or authorize the following services to the client named below on a non-emergent basis: physician, clinical, pharmaceutical, laboratory and podiatric. The primary pharmacy named on the card must provide or authorize all prescription drugs on a non-emergent basis.
    Dr. John Smith
    The Pill Box Pharmacy
12. The primary physician named on the card must provide or authorize the following services on a non-emergent basis: physician, pharmaceutical, clinical, laboratory and podiatric.
    Dr. John smith
13. Covered services are limited to Medicare deductibles and coinsurance
14. Services include Medicare deductible/coinsurance and Medicaid services.
15. No inpatient or long term care services are authorized. MPE client.
16. Organ Transplant Services are not covered.
17. Long term care services are not covered.
18. Medicaid services exclude long term care not covered under QMB.
19. Long term care services are not covered through_____ Mo/YR
20. Long term care services are not covered beginning _____ MO/YR
21. LTC services are not covered for the month(s) of _____ through_____ MO/YR MO/YR
22. Medicaid services excludes LTC not covered under QMB for _____ - _____ MO/YR MO/YR
23. Medicaid services excludes LTC not covered under QMB beginning_____ MO/YR
24. Medicaid services excludes LTC not covered under QMB through_____ MO/YR

Reduced Facsimile of Form HFS 1411CF

ILLINOIS DEPARTMENT OF HEALTHCARE AND FAMILY SERVICES
TEMPORARY MEDIPLAN CARD

VALID ONLY WITH SEAL

CASE ID: 94-106-00-123456
ELIGIBLITY PERIOD: 12/21/1999 THROUGH 12/31/1999

IMAGINARY, JANE DOE
45 ANYPLACE ROAD
YOUR TOWN, IL 60000

DATE ISSUED: 12/21/1999 CASE LOAD: 237
TOTAL NUMBER OF ELIGIBLE PERSONS = 1

ONLY THE FOLLOWING PERSONS ARE ELIGIBLE:

JANE DOE IMAGINARY ID#: 987654321 DOB: 09-26-1978
MEDICAID

**** NO MORE PEOPLE ****

MESSAGES

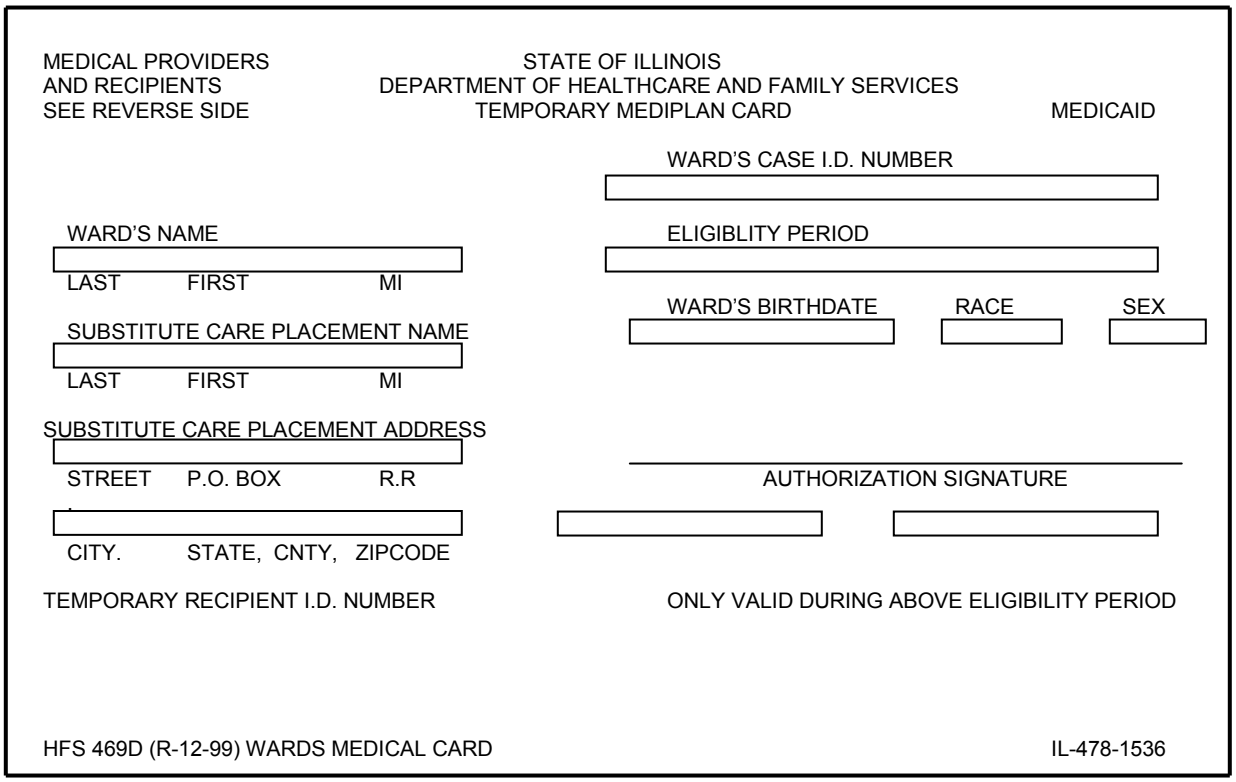
NOTICE TO RECIPIENT: This card is NOT Transferable.
Use by persons other than those named is illegal.
This TEMPORARY CARD IS NOT VALID IF IT HAS BEEN
ALTERED OR CHANGED IN ANY MANNER
TERM:K409 DATE: 12/22/99 TIME: 15:34:42

FOR HFS USE ONLY
SERIAL NO: 246801357
****
HFS SECURITY CODE
335221774786916

HFS 141CF

Note: To be valid, this form must have a HFS or DHS embossed seal.

Reduced Facsimile of Form HFS 469D



Note: This card is blue, with distinctive basket-weave pattern in background.

110 RECORD REQUIREMENTS

110.1 MAINTENANCE OF RECORDS

Providers are to maintain the following records:

- Any and all business records which may indicate financial arrangements between the provider and other providers in the program or other entities, or which are necessary to determine compliance with federal and State requirements, including, but not limited to:

    - business ledgers of all transactions;
    - records of all payments received, including cash;
    - records of all payments made, including cash;
    - corporate papers, including stock record books and minute books;
    - records of all arrangements and payments related in any way to the leasing of real estate or personal property, including any equipment;
    - records of all accounts receivable and payable; and
    - original signed billing certification forms for each voucher received (see Topic 130.5).

- Any and all professional records which relate to the quality of care given by the provider or which document the care for which payment is claimed, including, but not limited to:

    - medical records for applicants and participants in the Department's Medical Programs (copies of claims alone will not meet this requirement), including a record of ancillary services ordered as a result of medical care rendered by the provider; and
    - other professional records required to be maintained by applicable federal or State law or regulations.

The business and professional records required to be maintained are to be kept in accordance with accepted business and accounting practice and are to be legible.

Professional records documenting the history, diagnosis, treatment services, etc., of a Medical Assistance, All Kids, Transitional Assistance or State Family and Children Assistance patient are to be made available to other health care providers who are treating or serving the patient, without charge and in a timely manner, when authorized by the patient in writing.

110.2 RETENTION OF RECORDS

Business and professional records must be maintained for a period of not less than three years from the date of service or as otherwise provided by applicable State law, whichever period is longer, except that:

- if an audit is initiated within the required retention period, the records must be retained until the audit is completed and every exception resolved, and
- original signed billing certifications for every voucher received are to be retained not less that three years from the date of the voucher (see Topic 130.5).

110.3 AVAILABILITY OF RECORDS

All records required are to be available for inspection, audit and copying (including photocopying) by authorized Department personnel or designees during normal business hours. Such personnel or designees may include but are not limited to the Department's Office of Inspector General, representatives of the Medicaid Fraud Control Unit, law enforcement personnel, the Office of the Auditor General, and the federal Centers for Medicare and Medicaid Services (CMS). Such personnel or designees shall make all attempts to examine such records with minimum of disruption to the professional activities of the provider.

The provider's business and professional records for at least 12 previous calendar months are to be maintained available for inspection without prior notice by authorized Department personnel or designees on the premises of the provider. Department personnel shall make requests in writing to inspect records more than 12 months old at least two days in advance of the date they must be produced.

In the absence of proper and complete medical records, no payment will be made and payments previously made will be recouped. Lack of records or falsification of records may also be cause for a referral to the appropriate law enforcement agency for further action.

111 PRIOR APPROVAL PROVISIONS

Prior approval is required for the provision of certain medical services/items in order for payment to be made by the Department. Services/items requiring prior approval are identified in Chapter 200 of the Handbook that pertains to that type of service. Providers are responsible for obtaining prior approval for services/items to be provided. Copies of the appropriate forms and instructions for use in requesting prior approval are included in the appendix of the appropriate provider Handbook.

An approved request does not guarantee payment. Prior approval to provide services does not include any determination of the patient's eligibility. When prior approval is give, it remains the provider's responsibility to verify the patient's eligibility on the date of service and to confirm the patients continuing need for the service.

In general, in order for prior approval to be granted, items or services must be appropriate to the patient's needs, necessary to avoid institutional care, and medically necessary to preserve health, alleviate sickness, or correct a handicapping condition.

The information that must be submitted with a prior approval request may include but is not limited:

- Patient's name
- Patient's Recipient Identification Number
- Patient's age, address, and whether or not the patient resides in a long term care facility.
- Identification of the practitioner prescribing or ordering the service/item
- Diagnosis or diagnoses
- Description of service/item
- Treatment plan
- How long the service/item will be needed
- Purchase or rental cost
- For transports, both pick up site and destination

The exact information required will depend on the item or service for which prior approval is being requested. Refer to the appropriate Chapter 200 for further details.

To the extent possible, the request should show how the service/item is expected to correct or help the condition, and why the requested treatment plan is better than any other plan commonly used to deal with similar diagnoses or conditions. Anything unique to the medical condition or living arrangement affecting the choice of a recommended treatment plan or item should be explained. Approval is not transferable. When it is given, only the provider submitting the request may expect payment for the approved service/item.

The Department will not give prior approval for a service/item if a less expensive service/item is appropriate to meet the patient's needs. The Department will not approve purchase of equipment if the patient already has equipment which is adequate and sufficient to meet his/her medical needs.

Except for medical transportation requests, written notice of the disposition of requests for prior approval will be sent to the patient and to the provider. In the case of transportation requests, the DHS local office may advise the patient or provider orally at the time the prior approval decision is made. This will then be followed by a written approval sent to the transportation provider. The provider is responsible for retaining the written prior approval for audit purposes.

When a request is denied, the patient will be advised of his/her right to appeal the decision and to have a fair hearing. An appeal may not be made by the provider.

111.1 PRIOR APPROVALS OUTSIDE ORDINARY PROCESSING

The ordinary processing of a prior approval request for items such as, but not limited to, pharmaceuticals, durable medical equipment, prosthetics or disposable medical supplies may be bypassed if the service is needed to facilitate a hospital discharge or because of an unforeseen circumstance.

The provider supplying the item may contact the Department by telephone to provide information regarding the prior approval, including the date by which an authorization decision is need and all other information necessary for completion of the prior authorization review. When it is necessary to provide an item outside of routine business hours, approval via telephone must be requested the next business day. If not, the request will be handled as a routine post approval request. Once an approval is given by telephone, no further evaluation of the request will be made. Requests for renewal of such an approval, if needed, will be considered within the ordinary processing procedures for prior approval requests. Refer to the appropriate Chapter 200 for detailed instructions on obtaining prior approvals.

111.2 APPROVAL AUTHORITY FOR PRIOR APPROVAL REQUEST

Listed below are the various Department sections to be contacted by providers. They are specified by provider type and/or services.

For durable medical equipment and supplies, occupational, physical and speech therapies, podiatric items and services, communication and prosthetic devices, or home health agency services, contact:

Illinois Department of Healthcare and Family Services
Prior Approval Unit
Post Office Box 19124
Springfield, Illinois 62794-9124
1-877-782-5565 select option 5 from the automated menu
FAX # (217) 524-0099

Prior approval requests may also be submitted electronically through a REV vendor. See Topic 131.2 for an explanation of the REV system.

For drugs not included in the Department Drug Manual and Refill-Too-Soon override requests, contact:

Illinois Department of Healthcare and Family Services
Pharmacy Unit
Post Office Box 19117
Springfield, Illinois 62794-9117
1-800-252-8942 or 1-877-782-5565

PHARMACIES ONLY – Automated Voice Response System (AVRS) Available 24 hours, 7 days a week, including holidays – 1-800-642-7588.

For dental services which require prior approval, contact:

Doral Dental Services
DDS of Illinois – Authorizations
1201 North Port Washington Road
Mequon, WI 53092-3376
1-888-281-2076

For extraordinary modes of transportation, for example, helicopters and fixed-wing airplanes, contact:

Illinois Department of Healthcare and Family Services
Bureau of Comprehensive Health Services
Post Office Box 19116
Springfield, Illinois 62794-9116
1-888-782-5565
FAX (217) 524-7120 or (217) 524-4283

For approval of routine transportation within Illinois or to facilities normally utilized by Illinois residents, contact the patient's local FCRC.

Exception: For approval of routine transportation for All Kids Share and Premium Level 1 participants, contact the HFS Central All Kids unit at 1-877-805-5312. These cases can be identified by the 180 through 189 or 220 number in the Responsible Office portion of the case identification number. Refer to Topic 108.4 for further information or interpreting the case identification number.

For practitioners only, for any circumstances not outlined above, contact:

Illinois Department of Healthcare Family Services
Bureau of Comprehensive Health Services
P.O. Box 19115
Springfield, Illinois 62794-9115
1-877-782-5565
FAX # (217) 524-7120

Services which are not covered by the Illinois Medical Assistance Program may be available to DCFS wards through a prior approval process by the appropriate Regional Office of DCFS. Requests for prior approval for these services are to be submitted on the appropriate HFS prior approval request form direct to the Regional Office through which the DCFS ward is being served.

For managed care enrollees, the MCO designated on the MediPlan or All Kids card should be contacted for prior authorization for all non-emergency services. Prior authorization for emergency services is not required for managed care enrollees, but MCO authorization for post-stabilization services is required. MCOs provide 24 hour access to health care professionals designated to provide authorization services. Providers must make two documented good faith efforts to contact the plan for authorization of post-stabilization services. The plan must pay for covered post stabilization services if the plan was not accessible to the provider or if authorization was not denied within 60 minutes. The provider must continue to try to contact the plan after post stabilization services are rendered.

112 SUBMITTAL OF CLAIMS

This Topic addresses general requirements for claims submitted directly to the Department for payment. Other or additional requirements may apply when claims are processed by a fiscal intermediary, for example, dental claims submitted to the Department's dental contractor. General instructions for claims that are covered in part by Medicare or other payors can be found in Topic 120. Instructions for paper claim preparation and submittal for specific service or provider types are included in the Chapter 200 series and its associated Appendices.

112.1 VALID BILLING CODES

For billing purposes, the Department requires that ICD-9-CM diagnosis codes be used in the "Diagnosis Code" area of the UB-04 and NIPS claims forms. On non-institutional claim forms, all levels of Healthcare Common Procedure Coding System (HCPCS) codes, including CPT procedure codes and nationally assigned Medicare procedure codes are recognized. HCPCS codes can also be used in the "Revenue Code" area of the UB-04, if indicated. In the "Procedure Code" area of UB-04, HCPCS must be used if a procedure code is required. NDC codes are used for drugs and some medical supplies.

Codes other than as described above will not be honored for billing purposes and payments made in error for such billings may be recouped.

112.2 TIME LIMITS FOR CLAIM SUBMITTAL

With the exception of those claims that are received by the Department and immediately returned to the provider as being unacceptable for processing, all claims received are assigned a unique Document Control number (DCN) and computer processed. The DCN consists of the date the claim was received by the Department (expressed as a Julian date) plus an individual number to identify the specific claim. A Julian Date Calendar is provided in General Appendix 4.

A claim will be considered for payment only if it is received by the Department no later that 12 months from the date on which services or items are provided. This time limit applies to both initial and resubmitted claims. Rebilled claims, as well as initial claims, received more than 12 months from the date of service will not be paid.

The action taken on each claim processed is reported to the provider on Form HFS 194-M-1, Remittance Advice. Providers should resubmit claims only if their claims fail to appear in the MEDI System thirty (30) days after submission to the Department. The provider should prepare a new original claim for submittal to the Department. It is the responsibility of the provider to assure that a claim is submitted timely.

Exception: Claims are generated by the Department of Long Term Care providers, using Form HFS 3402, LTC Pre-Payment Report. Discrepancies on such claims are not to be rebilled as described above. LTC providers should consult Chapter C-200 for instructions on resolving missing claims or discrepancies

Claims which are not submitted and received in compliance with the foregoing requirement will not be eligible for payment by the Department and the state shall have no liability for payment thereof.

112.3 REQUIREMENTS WHEN BILLING ELECTRONICALLY

In order for enrolled providers to submit claims electronically, they must have completed and the Department must have on file an Agreement for Participation (HFS 1413). The Provider Information Sheet produced by the Department displays a "Y" associated with the item labeled Agreement for Participation (AGR) when an agreement is on file with the Department.

Note that electronic submission of claims may be suspended during a period of time when the Department is performing an audit of the provider. If this occurs, the Department will notify the provider that he or she must submit paper claims and when electronic billing may be resumed.

112.31 Electronic Claims Capture (ECC)

Providers may submit all non-institutional claims other than pharmacy claims, as well as institutional clams billed on form UB-04, electronically through Recipient Eligibility Verification (REV) vendors and the Medical Electronic Data Interchange (MEDI) Internet site. The Department accepts non-institutional claims in the X-12 837 Professional standard, Version 4010A and institutional claims in the X-12 837 Institutional standard, Version 4010A.

The Department has contracted with several REV vendors who will collect the claim data from providers and forward them to the Department in the proper format, acting as clearinghouses, if necessary. The REV vendors will make the necessary instructions for use of the appropriate electronic format available to providers. Each vendor may have different requirements for testing, pre-editing, reports, etc., and offer value added services. Providers should choose a vendor who best meets their needs. Information regarding REV vendors can be obtained from the Department's Web site or by contacting the Department at 1-877-782-5565.

Electronic claims can be submitted to the Department through a REV vendor or MEDI.

All electronically submitted claims will be subject to the same edits and be reported on a Remittance Advice in the same manner as paper claims. The same requirements for claim submission, including verifying patient eligibility, billing known insurance carriers, and reporting TPL payments, exist as for paper claims. Electronic

claims have the advantage of being entered into the Department's claims processing system more quickly.

Claims that require an attachment as well as adjustments to paid claims cannot be submitted electronically at this time. They must continue to be submitted to the Department on paper billing forms.

Each Remittance Advice that reports electronically submitted claims will be accompanied by the form HFS 194-M-C, Billing Certification.

The provider who provided the services and submitted the claim for payment must review the Remittance Advice and attest to the accuracy of the information thereon by signing the Billing Certification.

The same signature requirements that apply to the signing of a paper claim, as described in Topic 112.41 apply to form HFS 194-M-C, Billing Certification. The signed form must be maintained in the provider's records for three years from the date of the Remittance Advice to which it relates or for the time period required by applicable federal and State laws, whichever is longer.

112.32 Electronic Claims Processing (ECP)

Electronic Claims Processing (ECP) is the system by which providers may submit claims for pharmacy services to the Department electronically. For claims submitted via ECP, only the National Council of Prescription Drugs Program (NCPDP) Version 5.1 billing format is acceptable. Since this format is proprietary, providers must contact NCPDP to receive a copy of the format. NCPDP may be reached at (602) 957-9105 or via FAX at (602) 955-0749.

Three companies serve as transmitters for claims information from a pharmacy to the Department. The pharmacy may choose any one of the companies. They are as follows:

Company	Contact	Telephone Number
WebMD (Envoy Corp)	Help Desk	(800) 333-6869 Ext. 4001
WebMD (MedE America)	Client Services Department	(800) 433-4893
Tech Rx	NDC Help Desk	(800) 888-0412

All software created using the NCPDP formats must be tested and approved by the Department. Questions regarding ECP testing or to obtain a set of test conditions should be directed to the Bureau of Technical Support at (217) 524-7288.

112.4 REQUIREMENTS WHEN BILLING ON PAPER

112.41 Claims Preparation

To facilitate processing and to minimize chances for rejection or error in payment, it is recommended that claims be typewritten or computer printed. Refer to the Chapter 200 series and its Appendices for applicable guidelines

Claims must be legibly signed and dated in ink by the provider or his or her authorized representative. Any claim that is not properly signed or that has the certification statement altered will be rejected. A rubber signature stamp or other substitute is not acceptable.

An authorized representative may only be trusted employee over whom the provider has direct supervision on a daily basis and who is personally responsible on a daily basis to the provider. Such a representative must be designated specifically and must sign the provider's name and his or her own initials on each certification statement. This responsibility cannot be delegated to a billing service.

It is mandatory that claims to the Department for services be submitted only on original billing forms. Photocopies or other facsimile copies cannot be accepted for payment purposes.

112.42 Mailing of Claims

All claims with the exception of the UB-04 are to be mailed in the preaddressed envelopes supplied by the Department as specified in the Chapter 200 series and appendices. Any deviation from this requirement will delay payment. All other correspondence is to be mailed separately from claims, unless specified as a required attachment to a claim and addressed to the appropriate office as specified in the Chapter 200 series.

To expedite processing of claims, the following procedures should be used:

- review all forms for accuracy and completeness
- do not fold or mutilate claims
- do not staple, paper clip, or otherwise attach claims together
- mail as many claims as possible in one envelope place claims in envelope with all pages facing in the same direction

112.43 Ordering of Claims Forms and Envelopes

HFS provides required billing forms (with the exception of UB-04 claim form), adjustment forms, prior approval request forms and various types of pre-addressed mailing envelopes for submission of claims to the Department.

A provider must request forms using Form HFS 1517, Provider Forms Request, and mail it to the preprinted address on the top of the request form. See General Appendix 10 for sample form HFS 1517 and instructions for their completion.

The provider should submit requests for forms or envelopes at least three weeks in advance of needing the material. The Department will not mail forms (except Form HFS 1517) in response to telephone requests. To obtain the appropriate claim form number and mailing envelope number, refer to Chapter 200 for the type of service being billed.

In order to receive a supply of forms, a billing service must supply (in addition to the name of the company and its mailing address) at least one HFS provider name and that provider's HFS provider number.

UB-04 claim forms are not provided by the Department. Providers must purchase them from private vendors.

112.5 CLAIM PROCEDURES FOR MEDICARE COVERED SERVICES

Charges for deductible and coinsurance amounts due for Medicare covered services are to be submitted to the Department only after adjudication by the Medicare carrier or intermediary.

Services billed to the Illinois Medicare Part B Carrier or Durable Medical Equipment Regional Carrier (DMERC) as first payor will be "crossed over" to the Department electronically for consideration for payment of coinsurance or deductibles or both by the Department. Paper claims should not be submitted directly to the Department when the Medicare Remittance Notice shows a message or code stating that the claim has been forwarded to the Illinois Department of Healthcare and Family Services.

Providers who bill other Medicare carriers or intermediaries should continue to bill the Department for the patient liability by submitting a claim containing the same information as the claim adjudicated by Medicare with a matched Medicare Remittance Notice attached. **Exception:** It is not necessary to attach a Medicare Remittance Notice to UB-04 claims; however, Medicare payment information must be reflected on the claim submitted to the Department.

A claim that has been totally rejected for payment by Medicare may be submitted for payment consideration only when the reason for nonpayment is either that:

- the patient was not eligible for Medicare benefits or
- the service is not covered as a Medicare benefit.

In such instances, the Department is to be billed only after final adjudication of the claim by the Medicare carrier or intermediary.

For further information on the Department's payment policies for services to Medicare participants, refer to Topic 120.1. For detailed billing instructions on such claims, refer to Chapter 200.

112.6 CLAIMS PROCEDURES FOR RECIPIENT RESTRICTION PROGRAM (RRP) SERVICES

Claims for services to participants who have been restricted to a Primary Care Physician (PCP) or Pharmacy require no special forms or procedures as long as the services are provided by the Primary Care Physician or Pharmacy.

When restricted services are provided by the other providers, they require the written authorization of the PCP. Authorization is documented on a Form HFS 1662. A completed Form HFS 1662 must be attached to the claims(s) for restricted services. Form HFS 1662 may authorize one service date only. Therefore, the date of service on a claims(s) must be for the date specified on Form HFS 1662. Multiple services billed on a single claim form may be attached to a single (1) Form HFS 1662 provided that all dates of service are the same.

The Form HFS 1662 and the appropriate billing form are to be submitted to:

Illinois Department of Healthcare and Family Services
Post Office Box 19118
Springfield, IL 62794-9118

A supply of Form HFS 1662 may be obtained by contacting the Department by phone at 1-800-325-8823.

Billings for restricted types of care without Form HFS 1662 attached will be rejected. Rejection Code R29, “Recipient Services Restricted”, or Rejection Code R30, “Care Not Authorized by Primary Physician,” will appear on the Remittance Advice when claims are submitted for restricted services without an attached Form HFS 1662 completed by the Primary Care Physician or Primary Care Pharmacy.

These claims should be resubmitted to the address listed above only if one of the following are attached:

- A completed Form HFS 1662 from the PCP, authorizing the service(s) and date(s) of service.
- A copy of the participant’s MediPlan Card or All Kids Card or Temporary Card if the RRP restriction message and the PCP designation were not printed on the card on the date(s) the service was rendered.

If neither of these are available, the claim should not be resubmitted as payment cannot be authorized.

113 SPENDDOWN

The spenddown program provides Medical Assistance to participants who would otherwise be ineligible because of income or assets or both which exceed the Department's standards.

113.1 SPENDDOWN EXPLAINED

Spenddown is similar in concept to a patient deductible in a private insurance plan, with three major exceptions:

1. The participant's spenddown obligation is determined on a monthly basis. (Deductibles in most insurance plans are determined on an annual basis.)
2. The amount of that monthly spenddown obligation is based upon the participant's income and assets. (Most insurance plans have a standard deductible regardless of patient income.)
3. When spenddown is met in the middle of a month, the decision as to which bills are the patient's responsibility and which are the Department's is made chronologically based on date of service. (Most insurance plans base this decision on date of receipt of the bills.)

Although enrolled in the Medical Assistance program, spenddown participants do not automatically receive a MediPlan card each month. MediPlan Cards are only issued for the month (or portion thereof) for which participants have demonstrated that incurred or paid medical expenses equal the spenddown obligation by presenting medical bills and receipts to the FCRC. In the case of participants who have private insurance or other Third Party Liability (TPL) coverage, that portion of the medical bills and receipts which is paid by the TPL resource is not counted toward meeting the spenddown obligation.

Because the participant's eligibility can be determined only after he or she receives medical bills or receipts demonstrating that the spenddown obligation has been met, it is not unusual for the MediPlan Card to be issued several months after the month it covers.

If a provider accepts an individual as a Medicaid participant, all medical charges up to the amount of the spenddown obligation are the participant's responsibility.

For example:

- If a provider renders a service to a participant with a $300 spenddown, and the Department's maximum rate for the service is $275, and the private pay rate is $350, the provider may only bill the participant for the $300 spenddown amount. The provider may not bill the participant at the private pay level, or
- a participant's spenddown obligation is $60, and he or she receives a medical service for which the provider charges $80 but for which the Department's maximum rate is $65. In this instance, the spenddown obligation would be satisfied by the provider's charges, the participant would be responsible for the

$60 spenddown obligation and the Department would pay $5. The participant could not be held responsible for the unpaid balance.

113.2 SPLIT-BILL DAY

Responsibility for bills on the day the spenddown obligation is met is often shared between the patient and the Department. This is referred to as “split-bill day”. The FCRC will notify the participant that spenddown has been met, which bills the participant is responsible for paying and which bills should be sent to the Department for payment. The FCRC will send Form HFS 2432, Split-Billing Transmittal, to the participant for each provider who is eligible for payment from the Department on the split-bill day. The participant is responsible for taking these forms to the medical provider. Upon request, the FCRC may send a Form HFS 2432 directly to the medical provider.

The Split-Billing Transmittal is issued only for those providers who are eligible for payment for services rendered on the split-bill day. No Form HFS 2432 will be issued for those bills which are totally the responsibility of the patient.

When any services are billed for a date that is determined to be a split-bill day, the Split-Billing Transmittal must be attached to the claim. Providers can determine the need for a Form HFS 2432 when billing by viewing the MediPlan Card. If there is a split-bill day, the MediPlan Card will contain a message regarding the need for Form HFS 2432 and identifying the service date affected.

If services were provided on the split-bill day and a Form HFS 2432 has not been received, the provider should determine whether or not one has been issued. This can be accomplished by viewing the notice sent to the participant or by contacting the FCRC. However, no billing should be submitted to the Department unless Form HFS 2432 has been received and attached to the Department claim. Unless a Form HFS 2432 has been received, the participant remains responsible for the charges incurred on the beginning date of eligibility.

Specific instructions for completing a claim form to which Form HFS 2432 is attached can be found in the Chapter 200 Appendices.

Reduced Facsimile of Form HFS 2432

State of Illinois 4 (3 Year)
Department of Human Services

SPLIT BILLING TRANSMITTAL FOR MANG SPENDDOWN PROGRAM

To:
This form is your authorization to bill the Illinois Department of Healthcare and Family Services for the services described below if you are currently eligible to participate in the Medical Assistance Program.

This is to certify that_____
Recipient Name Recipient #

_____is eligible to receive medical assistance effective_____/_____/_____
Date of Birth

Case Name: _____
Last First Middle

Case I.D. _____ Provider#: _____
Cat. L.O. Grp. Basic

Description of Item/Service_____

Date of Service_____ HFS Control Number_____ of _____

Total Charge $_____ Less Recipient Liability Amount $_____

You are responsible for collecting the Recipient Liability Amount which is to be entered in the TPL and Deduction fields on a MMIS Invoice.

Attach this form to the back of your Medicaid or Medicare Crossover invoice and submit in a special envelope per Department Handbook instruction. Please consult your provider handbook for detailed billing instruction regarding the coding of Spenddown information on your particular invoice.

_____
Local Office Administrator

_____
Local Office

_____
Date

Local Office Address Stamp

HFS2432 (R-10-98) IL478-0704

114 PATIENT COST-SHARING

Payments made by the Department to providers for services to eligible participants are considered payment in full. If a provider accepts the patient as a Medical Programs participant, the provider may not charge eligible participants for copayments, participation fees, deductibles, or any other form of patient cost-sharing, except as specifically allowed in this Topic or in Topic 113, Spenddown. In no other instance may any form of patient cost-sharing be charged to eligible participants for any covered services under any of the programs described in Topic 100 of this handbook.

Providers may not make arrangements to furnish more costly services or items than those covered by the Department on condition that patients supplement payments made by the Department.

114.1 ALL KIDS COPAYMENTS

For children covered by All Kids Share or All Kids Premium, copayments may be charged by health care professional whenever the services are performed in an office or home setting, except as listed below. No copayments may be charged for:

- Visits scheduled for well-baby care, well-child care, or age appropriate immunizations
- Visits in conjunction with the Early Intervention Program
- Visits to health care professional or hospitals made solely for radiology or laboratory services
- Speech therapy, occupational therapy, physical therapy and audiology
- Durable medical equipment or supplies
- Medical transportation
- Eyeglasses or corrective lenses
- Hospice services
- Long term care services
- Case management services
- Preventive or diagnostic services

Providers are not required to collect copayments.

Hospitals may charge copayments once per inpatient admission or outpatient encounter (including the emergency room).

No copayments may be charged for services provided to children in American Indian or Alaska Native families enrolled in All Kids Share or All Kids Premium. Providers should disregard copayment charge messages printed on All Kids Cards if a family declares American Indian or Alaska Native ancestry. Copayments cannot be charged for any child in that family. For families who declare American Indian or Alaska Native ancestry to the Department, a message will appear on the All Kids Cards indicating that no copayments may be charged.

Copayment information is printed on the front of the All Kids Identification Card. General Appendices 12 and 13 provides a detailed listing of services for which All Kids Share and All Kids Premium copayments may be charged and the amount of allowable copayments.

Copayments are capped at a maximum out of pocket expense for a family during a 12 month eligibility period. Families are responsible for collecting copayment receipts and submitting them to the Department once they have reached the cap. Upon determining that the copayment cap has been satisfied, the Department will:

- send a notice to the family stating that the copayment cap has been satisfied and the date satisfied,
- print a message that the copayment cap has been satisfied, and the date satisfied, on the monthly All Kids Identification Card, and
- update MEDI and REV to reflect that the copayment cap has been reached.

Providers have the option of either charging copayments, or not. The Department will not require providers to deliver services in instances when a co-payment is charged but is not paid. However, if the provider elects to charge co-payments, the provider will be responsible for refunding the family copayments they collect after the family has reached the copayment cap.

All Kids Share and Premium Level 1 copayments are in addition to any payments made by the Department. They are not to be shown on the claim submitted to the Department. If a provider enters the patient co-payment amount on the claim in error, as a patient contribution or a third-party payment, this will cause the Department's payment to be reduced.

114.2 COPAYMENTS FOR MEDICAL ASSISTANCE PROGRAMS

Participants in the Department's Medical Assistance Programs may be subject to a copayment as described below.

114.21 Fee-For-Service Copayments

A copayment may be charged to an adult participant in the Medical Assistance Program for each fee-for-service office visit to a physician, chiropractor, podiatrist or optometrist and for prescription drugs (legend drugs) received through a pharmacy, with certain exceptions. No provider of these services may deny service to a participant who is eligible for service on account of the participant's inability to pay the cost of the copayment. See Appendix 13 for specific codes subject to the co-payment. For further information, refer to 89 Ill. Adm. Code 140.402.

The Department will automatically deduct the copayment on applicable services from the payable amount and will report the deduction on the point-of-sale electronic billing system for pharmacies and on the remittance advice for all affected providers. When billing the Department, providers should continue to bill their usual and

customary charge and should not report the co-payment on the claim or electronic submission.

Reimbursement and copayments under the All Kids Share Plan and All Kids Premium Plan are not subject to this policy. See Topic 114.1 for an explanation of copayments under all Kids Share and premium.

114.22 Copayments for Inpatient Hospital Stays

A copayment may be charged to an eligible participant for certain inpatient hospital stays. The Department deducts such copayments when calculating the amount of its payment to the hospital. For further information, refer to 89 Ill. Adm. Code 148.190.

114.3 MEDICARE CO-INSURANCE AND DEDUCTIBLES

Medical Program participants may not be charged for Medicare co-insurance and deductibles, regardless of whether the Department pays all, some or none of the charges. Refer to Topic 120.12 for further details.

114.4 STATE RENAL DIALYSIS PROGRAM PARTICIPATION FEES

Participants in the State Renal Dialysis Program may be responsible for payment of a portion of the cost of covered dialysis services. This is referred to as the patient's monthly participation fee. It is determined by the Department on an annual basis. The Renal Dialysis Center is notified of the amount in writing, via a computer-generated Eligibility Report for Dialysis Patients.

The renal dialysis center may charge State Renal Dialysis Program patients for services up to the amount of the participation fee. Such charges will be automatically deducted from the patient's monthly dialysis claims submitted to the Department.

Other than the monthly participation fee, dialysis centers may not charge a State Renal Dialysis Program participant for any covered dialysis service for which a claim is submitted to the Department.

114.5 STATE HEMOPHILIA PROGRAM PARTICIPATION FEES

Participants in the State Hemophilia Program may be responsible for payment of a portion of the cost of covered services. This is referred to as the patient's annual participation fee. It is determined on an annual basis. Both the participant and the Hemophilia Center are notified of the amount in writing, via a letter from the Department.

Providers may charge State Hemophilia Program patients for covered services up to the amount of the participation fee. Such charges will be automatically deducted from the first bill or bills submitted to the Department.

Once the patient's annual participation fee has been met, a State Hemophilia Program participant may not be charged for any covered service for which a claim is submitted to the Department.

114.6 LONG TERM CARE FACILITY GROUP CARE CREDITS

Participants in the Department's Medical Programs who reside in Long Term Care (LTC) facilities may be responsible for payment toward the cost of covered services. This payment is referred to as the group care credit. It is determined for each resident on a monthly basis by the FCRC. The FCRC notifies the resident of the amount in writing. Refer to Topic C-212 in the Long Term Care Provider Handbook for an explanation of this process.

Facilities may charge residents for covered LTC services up to the maximum monthly payment rate established by the Department for those services, or their group care credit that month, whichever is less. Such charges will be automatically deducted from the amount that would otherwise be paid to the LTC facility by the Department.

Refer to Topic C-230 in the Long Term Care Provider Handbook for a listing of services covered by the Department's monthly payment to the facility.

114.7 HOSPICE PATIENT GROUP CARE CREDITS

When a hospice patient resides in a Long Term Care Facility, the hospice is responsible for payment of the LTC room and board charges. In this case, the patient's group care credit (if any) described in Topic 114.6 is automatically deducted from amount that would otherwise be paid to the hospice by the Department. Refer to Chapter K-200, Handbook for Hospice Providers for an explanation of this process.

120 OTHER PAYMENT SOURCES

The Illinois Department of Healthcare and Family Services is, by federal and State law, the payor of last resort. Payment can be made through the Department's Medical Programs only after all other known resources for payment, both private and governmental, have been explored and exhausted.

Examples of third party resources include Medicare, private health insurance, liability insurance, Worker's Compensation, Civilian Health and Medical Program for the Uniformed Services (CHAMPUS), Veterans Administration benefits, Black Lung benefits, etc.

It is the responsibility of the provider to ascertain from each patient whether there is a third party resource that is available to pay for the services rendered. In an effort to aid providers in situations where a third party resource is known to the Department, the third party liability (TPL) resource coverage code is printed on the MediPlan or All Kids Card (see Topic 108); however, providers retain the responsibility for determining the status of a patient's eligibility for third party coverage and benefits prior to making charges to the Department.

In general, where identifiable third party resources exist, claims must be submitted to and adjudicated by the liable third party(ies) before the Department can consider a claim for payment. Refer to the Chapter 200 series for more specific instructions on billing services that may be covered by TPL.

The Department will make no payments in instances where the total payment to the provider from the third party resource(s) exceeds the established Department rate for the services provided.

120.1 MEDICARE

Medicare is the program authorized by Title XVIII of the Social Security Act which provides health insurance for most individuals age 65 or over, and for others regardless of age who meet disability requirements. Medicare benefits include hospitalization and related part (Part A) and supplementary medical services (Part B). The Medical Assistance Program complements and supplements Medicare program benefits to Medical Assistance participants by payment of deductible and coinsurance obligations in some instances and by providing coverage of additional medical services.

The MediPlan Card issued to participants (see Topic 108) indicates participant eligibility for Medicare to the extent that such eligibility is known to the Department.

120.11 Assignment of Benefits

Providers must accept assignment of Medicare benefits for services to Medicare eligible patients for which payment is sought from the Department, and so indicate by checking the appropriate box on the claim form.

In recognition of the difficulties encountered by providers in obtaining patient signatures, the Social Security Administration permits the Department to obtain participant signatures assigning payment to providers. The Department, through an interagency agreement with DHS, obtains signed assignment statements for all participants eligible for Medicare Part B benefits. Therefore, this section of the claim form can be completed indicating that the signature is on file with DHS. For more detailed instruction on completing this portion of a claim, refer to Chapter 200.

120.12 Medicare/Illinois Medical Assistance Program Relationship

If the MediPlan Card has a designation of QMB/MEDICAID, the individual is a Qualified, Medicare beneficiary (QMB) in addition to being an Illinois Medical Assistance (Medicaid) participant. Billings for services rendered are to be submitted to Medicare first. After Medicare adjudicates the claim, the Department's payment policies are as follows:

- The amount of Medicare payment is compared with the Department's maximum rate for the service. The Department will pay the deductible and coinsurance to the extent that such payment plus Medicare's payment does not result in an amount that exceeds the Department's maximum. If the payment from Medicare exceeds the Department's maximum rate for the service, the claim will appear on the Remittance Advice as approved, but no payment will be made.

- If there was a service on the bill to Medicare which is not covered by Medicare but is covered by the Medical Assistance program, the Department will pay (at Department rates) for the service.

- If a service is covered by Medicare but not by the Medical Assistance program, the Department will pay only the full amount of deductible and coinsurance.

If the MediPlan Card has designation of QMB ONLY, the Medicare beneficiary (QMB) is not eligible for Illinois Medical Assistance (Medicaid) services. The following payment policies apply:

- If a service is covered by Medicare but is not a covered service in the Medical Assistance program, the Department will pay the full amount of the deductible and coinsurance.
- If the Medicare service is also covered by the Medical Assistance program, the amount of Medicare payment is compared with the Department's maximum rate for the service. The Department will pay the deductible and coinsurance to the extent that such payment plus Medicare's payment does not result in an amount that exceeds the Department's maximum rate. If the payment from Medicare

exceeds the Department's maximum rate for the service, the claim will appear on the Remittance Advice as approved, but no payment will be made.

120.2 HEALTH INSURANCE

If the provider identifies health insurance that is not shown on the Department's medical card, or the insurance coverage shown on the card is no longer in force, notification is to be made to the address below.

Illinois Department of Healthcare and Family Services
Third Party Liability Section
1130 South Sixth Street
P.O Box 19120
Springfield, Illinois 62794-9120
Telephone: (217) 524-2490
Fax: (217) 557-1174

120.3 PERSONAL INJURY CASES

It is the responsibility of the provider to notify the Department of any request from attorneys, insurance carriers, or participants for release of participant information.

Address requests pertaining to Cook County and out-of-state residents to:

Illinois Department of Healthcare and Family Services
Technical Recovery Unit
32 W. Randolph, 13th Floor
Chicago, Illinois 60601

Address requests for all other Illinois residents to:

Illinois Department of Healthcare and Family Services Technical Recovery Unit
2200 Churchill Road, Bldg. A
Springfield, Illinois 62702-3406

120.4 EXCEPTION FOR BILLING OTHER PAYMENT SOURCES FOR PREVENTIVE SERVICES FOR CHILDREN AND PREGNANT WOMEN

Physicians providing services to women with a diagnosis of pregnancy or preventive services to children are not required to bill a client's private insurance carrier prior to billing the Department. Charges may be billed immediately to the Department. The Department will collect information regarding paid services and assume responsibility for the collection of the third party benefits.

In making the decision to bill the Department first, the provider should be cognizant of the possibility that the third party payor might reimburse the service at a higher rate than the Department, and that once payment is made by the Department, no additional billing to the other third party payor is permitted.

130 PAYMENT PROCESS

No attempt will be made by the Department to process unacceptable claim forms, such as unsigned claims, photocopies, forms other than those supplied or specifically approved by the Department, and illegible forms. Unacceptable forms will be returned to the provider for correct preparation and resubmittal.

Each service billed on a claim, whether it is an individual service or an all-inclusive or bundled package, is considered separately. One of three actions may be taken on a service billed: the service may be paid, rejected, or suspended for further review and final action.

130.1 REMITTANCE ADVICE

Form HFS 194-M-1, Remittance Advice, will be mailed separately to correspond with each warrant (check) issued to a provider. The Remittance Advice reports the status of claims and adjustments processed. See General Appendices 7 and 8 for an explanation of the information that will appear on the Remittance Advice.

130.2 PAYMENT

When payment is made, it will be made in accordance with Department standards and rate for the services(s) provided. Payment will be made by a State warrant (check) issued through the Office of the State Comptroller. Warrants and Remittance Advices are processed on the same day, but sent in separate mailings.

130.21 Designation of Payee

At the time of initial enrollment with the Department, a provider has the opportunity to designate the address to which warrants are to be sent. Certain types of providers also may designate alternate payees. Information specifying conditions under which a group practice or an institution may be designated as payee is included in materials issued to providers upon enrollment for participation. If a provider has more that one payee listed with the Department, each claim submitted for payment must specify the payee to which the warrant is to be mailed.

Changes in payee designation or addresses are to be submitted to the Department as they occur, to ensure that warrants are not sent to the wrong address or payee. Refer to Topic 201.4 for instructions on updating provider information on file with the Department.

In as much as federal regulations prohibit assignment of Medical Assistance payments or payment by the Department to or through a factor, any arrangements where assignments have been made or power of attorney has been granted will have no effect on the Department’s action with regard to delivery of warrants.

130.22 Electronic Funds Transfer

The Electronic Funds Transfer (EFT) option allows providers to have payments electronically deposited into their bank account. EFT must be requested by the payee, not by the provider. All payees receive a paper Remittance Advice for medical payments, even if they choose to receive payments electronically. EFT can be arranged by contacting the State Comptroller's Website at http://www.ioc.state.il.us/

If provider does not wish to use EFT, hard copy or paper warrants will be mailed.

130.3 REJECTION OF CLAIMS

A service which cannot be paid due to errors that cannot be corrected by the Department will be rejected. The service will be identified on Form HFS 194-M-1, Remittance Advice, with the specific error(s) that rendered it unpayable.

A rejected service will be considered for payment only if all errors can be and are corrected and the corrected claim is resubmitted on timely basis. To be considered timely, the corrected claim must be received within 12 months of the date of service. Refer to the Error Code listing in General Appendix 5 for an explanation of the rejection reason(s) and the possible corrective action to be take prior to contacting the Department.

It is important for the provider to verify all information on the claim, especially the participant eligibility. If a participant is not eligible for a date of service, the claim cannot be rebilled. Refer to Topic 108 for more information on verification of participant eligibility. Refer to Topic 131 for general information on assistance in resolving billing problems.

130.4 SUSPENSION OF CLAIMS

A service that cannot be adjudicated when first processed due to special handling requirements or the need for error correction by the Department will be temporarily suspended. If any service section on a claim form must be reviewed, the entire claim will be held in suspense pending adjudication of the suspended service section. Such a claim will be reported on the Remittance Advice as suspended.

Services listed as suspended are not to be rebilled. Suspended services will appear on a later Remittance Advice when they have been adjudicated as either paid or rejected.

130.5 BILLING CERTIFICATION

Paper claim forms all contain a certification statement, which the provider is required to sign. By signing the form, the provider is attesting to the accuracy of the information contained therein.

Electronic claims and claims created by the Department contain no such certification, nor is there a way for the provider to sign electronic claims at the time of submittal. Instead, the Department has instituted a post-payment certification as described below.

A copy of Form HFS 194-M-C, Billing Certification, accompanies each remittance advice which contains an electronically submitted paid service or a service paid as a result of a claim created by the Department.

It is the responsibility of the provider who provided the service and submitted the claim for payment to review the Remittance Advice and sign the Billing Certification form attesting the accuracy of the information therein.

The same signature requirements that apply to the signing of a paper claim, as described in Topic 112.41, apply to Form HFS 194-M-C. The signed Billing Certification form must be maintained in the provider's records for three years from the voucher date to which it relates or for the time period required by applicable federal and State laws, whichever is longer.

131 BILLING INQUIRY PROCESS

Situations will arise when a provider finds it necessary to contact the Department regarding claims. Providers are reminded to first check Chapter 200 of the applicable provider handbook to ensure that proper billing procedures have been followed.

The Department is committed to giving providers options in the methods by which they obtain information from the Department. Providers should evaluate the available options and choose the method that best meets their needs.

131.1 PHONE AND MAIL INQUIRES

The Department has billing consultants to assist providers in resolving billing issues.

The provider should have the following information ready prior to contacting a consultant for a billing inquiry:

- The patient's name and Recipient Identification Number
- The provider's name, Illinois Medical Assistance provider number and NPI
- Type of claim
- Date of service
- Voucher and Document Control Number, if the claim has already been submitted and reported on a Remittance Advice.

Addresses and phone numbers of Department contacts for various subjects or specific provider types are listed following the Table of Contacts at the front of Chapter 100.

Written inquiries are to be mailed separately from claims. They are not to be mailed in the preaddressed envelopes provided by the Department for mailing claims and other specific forms.

131.2 RECIPIENT ELIGIBILITY VERIFICATION (REV) SYSTEM

The Recipient Eligibility Verification (REV) system is an interactive electronic system. REV allows providers to:

- verify a participant's eligibility
- submit claims electronically
- check the status of claims in processing
- determine which claims have been paid and the amount paid
- determine which claims have rejected and the reason for rejection
- download batches of claim information

Durable Medical Equipment (DME) providers can electronically submit prior approval requests through the REV system. Also, Long Term Care (LTC) providers can use the REV system to electronically transmit bed reserve information, discharge information and Medicare payment status.

Participant information available through the REV system includes but is not limited to:

- eligibility for the Medical Assistance Program
- eligibility for All Kids
- eligibility for the Transitional Assistance Program and the State Family and Children Assistance program (City of Chicago)
- MCO enrollment
- Recipient Restriction Program (RRP) status
- participant Medicare coverage
- participant health insurance (TPL) coverage

Providers can access the REV system through vendors who are independent contractors who have agreements with the Department to provide this service. REV vendors provide this access by various methods, including:

- standardized software for use on existing PCs
- point-of-service devices
- custom programming of a provider's existing computer system to accept and transmit the Department's data

A listing of the current REV vendors is available on the Department's Web site at http://www.hfs.illinois.gov/rev/

All current REV vendors also act as clearinghouses for other public and private payors. In this role, REV vendors offer services beyond those related to the Department's programs. For example, these vendors may offer general computer accounting support, preliminary claim editing, accounts receivable posting, and claims submittal to various third party payors. Providers pay the REV vendors for whatever mix and volume of services are selected.

Providers are encouraged to contact all vendors on the list to determine which vendor will best meet the provider's needs. Providers should consider whether the provider's computer will be able to access a vendor's system. Additionally, providers should check the vendor's charges for use of the system and determine whether there are services other than those listed above which the REV vendor offers.

132 ADJUSTMENTS

When the Department reports an incorrect payment on Form HFS 194-M-1, Remittance Advice, the error is corrected and supplemental payments or recoveries are made via an adjustment process. This ensures that Department's claims history files reflect the corrected information.

If the error is due to a computer problem in the Department's data system, the Department may initiate the adjustments. If this occurs, the adjustments will be reflected on a remittance advice and providers will need to take no adjustment action.

In all other instances, the provider must take action to ensure that the payment is corrected.

132.1 PHARMACY ADJUSTMENTS

Pharmacy services paid electronically may be adjusted electronically via the Department's point of sale system, using the appropriate National Council of Prescription Drug Programs (NCPDP) protocol. Services requiring adjustment that cannot be submitted electronically must be submitted on paper (HFS 1410) as a void transaction. The void transaction may be followed by the submission of a new invoice reflecting the correct claim information.

Pharmacy services submitted on paper claims must be adjusted using the process described in Topic 132.3

132.2 LONG TERM CARE (LTC) FACILITY ADJUSTMENTS

LTC facilities do not complete adjustment forms for incorrect payments. The Department initiates adjustments on a monthly basis to reflect corrected or changed information that may alter payment amounts. LTC facilities should refer to Topic C-263 of the Handbook for Nursing Facilities for a description of the adjustment system

Exception: If a LTC facility bills the Department directly for ancillary services, such as supplemental oxygen, and is paid an incorrect amount, such claims must be adjusted using the process described in Topic 132.3.

LTC facilities are responsible for immediately reporting to DHS or to HFS any corrections or changes in information that may affect payments. This includes but is not limited to resident death, discharge or changes in income.

132.3 ALL OTHER ADJUSTMENTS

Adjustment can only be made on paid claims. If a provider becomes aware that a claim has been submitted that will require an adjustment, no corrective action can be taken until the claim is adjudicated and appears on a Remittance Advice. As soon as the claim has been reported as a paid claim on a Remittance Advice, the provider

should submit an Adjustment form to correct the payment. Copies of Adjustment forms and instruction for their completion are provided in General Appendix 6.

133 REFUNDS

Although the Adjustment process in Topic 132 should generally be used whenever incorrect payment has occurred, there may be instances in which a provider considers it necessary to refund an overpayment to the Department.

To ensure that a refund or returned check is processed accurately and that the Department's records are adjusted appropriately, special care should be taken to ensure that correct and sufficient information is provided. For all types of providers other than Long Term Care facilities, if questions arise about the refund process, if the required documentation is not available or if the process described below does not seem to fit the situation requiring the refund, the provider should contact a billing consultant at 1-877-782-5565. LTC providers should contact the Bureau of Long Term Care at 217-782-0545 for instructions in any situation requiring a refund.

Procedure: With the refund check, the provider should submit a copy of the appropriate Adjustment form. Refer to General Appendix 6 for instructions on completing Adjustment forms. The provider should also submit a copy of the Department-generated Remittance Advice which was received with the incorrect payment or overpayment. The Remittance Advice should be marked to clearly indicate which payments are being refunded. Following these instruction will ensure that the Department has all of the information necessary for processing the refund and adjusting the Department's claims history files.

The provider must ensure that the total of all the individual service adjustments equals the refund check amount. Verification of the Department's receipt of the refund and processing of the adjustments will be reported on a future Remittance Advice.

When a refund is made via a check written on the provider's own bank account, the check should be made payable to the Illinois Department of Healthcare and Family Services. The provider should not mix payment refunds for various provider types on one check, i.e., hospital and non-institutional services. Separate refund checks are to be submitted because the refunds will be processed by the Department in two separate refund systems

Refund checks for services billed on the UB-04 should be sent to the following address:

Illinois Department of Healthcare and Family Services
Hospital Adjustment Unit
P.O. Box 19128
Springfield, Illinois 62793-9128
Telephone: 1-877-782-5565

Pharmacy refund checks should be sent to the following address:

Illinois Department of Healthcare and Family Services
Drug Unit
P.O. Box 19117
Springfield, Illinois 62794-9117
Telephone: 1-877-782-5565

Non-Institutional Provider refund checks should be sent to the following address:

Illinois Department of Healthcare and Family Services
Adjustment Unit
P.O. Box 19101
Springfield, Illinois 62793-9101
Telephone: 217-524-4597

Third Party Liability (TPL) refund checks should be sent to the following address:

Illinois Department of Healthcare and Family Services
Bureau of Collections, Third Party Liability
P.O. Box 19140
Springfield, Illinois 62794-9140
Telephone: 217-785-1753

134 AUDITS

All services for which claims are submitted to the Department are subject to audit. Audits are an important and necessary part of the Department's monitoring of health care facilities and services, as required by the federal and State law. Providers are selected for routine audit by a random sampling of billings processed and by other criteria determined by the Department. The initiation of audit proceedings should not be construed as an accusation of any wrongdoing on the part of the provider.

During an audit, the provider shall furnish to the Department, or to its authorized representative, pertinent information regarding claims for payment. Should an audit reveal that incorrect payments were made, or that the provider's records do not support the payments that were made, the provider shall make restitution.

The Department's procedure for auditing providers may involve the use of sampling and extrapolation. Under this procedure, the Department selects a statistically valid sample of the case for which the provider received payment for the audit period in question and audits the provider's records for those cases. All incorrect payments determined by an audit of the cases in the sample are then totaled and extrapolated to the entire universe of cases for which the provider has been paid during the audit period. Where sampling techniques are specific to the type of provider or claim being audited, additional details will be provided in Chapter 200.

The Department will recover all overpayments and take other action as appropriate. This may include seeking the termination of providers, in accordance with 89 Illinois Administrative Code, Part 104, Subpart C. For a more complete description of the recoupment process, refer to Topic 135.

135 RECOUPMENT RESULTING FROM AUDITS

The Department will recover payments when it is verified that overpayments have been made to a provider due to improper billing practices. The determination of overpayment will be based on Administrative Rules and Department policy and procedures as stated in the applicable Handbooks, or as evidence by statistical data on program utilization compiled from claims paid.

The provider will be notified in writing of the nature of any discrepancies, the method of computing the dollar amount which is to be refunded, and any further actions which the Department may take in the matter.

If the Department's findings were based on sampling and extrapolation, the provider may present evidence to the review coordinator to show that the sample used by the Department was invalid and, therefore, cannot be used to project overpayments identified in the sample to total billings for the audit period.

If the Department does not concur with the provider's position on the audit results, the Department's audit results stand. The provider receives written notification of the finding. If the provider remains in disagreement with the Department actions with respect to the audit, he or she may, within 10 days of receipt of the written notification, submit a request for a hearing. The notification specifies to whom the request for a hearing must be submitted.

The Department will notify the provider in writing of the date, time, and place of the review hearing. See 89 Illinois Administrative Code, Part 104, Subpart C, for complete details of the hearing process.

The provider may conduct an audit of 100% medical records of payments received during the audit period and present the results of such an audit at the hearing. Any such audit should demonstrate that the provider's records for the unaudited services provided during the audit period were in compliance with the regulations, provider Handbooks, and other written requirements of the Department. The provider should be prepared to submit supporting documentation to demonstrate the compliance.

136 FRAUD IN THE DEPARTMENT'S MEDICAL PROGRAMS

Providers are expected to obey all laws, civil and criminal, State and federal regulations, and Department policies pertaining to delivery of and payment for health care. The Department actively monitors all claims for payments to identify suspicious activities.

Providers suspected of fraud shall be criminally investigated and, when appropriate, prosecuted in state or federal court.

Providers suspected of fraud or abuse shall be reviewed to determine the propriety of continuing their participation in the Department's Medical Programs

The Department may suspend payments to providers indicted for health care fraud during the pendency of the indictment.

For purposes of participation in the Department's Medical Program, the Department defines fraud and abuse in the following manner:

Fraud: Knowing and willful deception or misrepresentation, or a reckless disregard of the facts, with the intent to receive an unauthorized benefit.

Abuse: A manner of operation that results in excessive or unreasonable costs to the Department's Medical Programs.

Title XIX of the Social Security Act, under which the Medical Assistance Program is administered, provides federal penalties for fraudulent acts and false reporting.

Providers are subject to State and federal laws pertaining to penalties for vendor fraud and kickbacks (305 ILCS 5/8A-3).

Program participants, providers or other individuals who have information regarding possible fraud or abuse should call the Fraud and Abuse Hotline, at 1-800-252-8903.

140 ADVANCE DIRECTIVES

An advance directive is a written instruction, such as a living will or durable power of attorney for health care, recognized under State law and relating to the provision of such care when the individual who executed the advance directive is incapacitated.

Under Illinois law, competent adults have the right to make decisions regarding their health care. The courts of this State have recognized that this right should not be lost when a person becomes unable to make his or her own decisions. Therefore, people have the right to accept or refuse any medical treatment, including life-sustaining treatment. In order to enable them to make these decisions, patients have the right to be adequately informed about their medical condition, treatment alternatives, likely risks and benefits of each alternative and possible consequences.

The law requires that patients be informed of the advance directives available to help assure that their wishes are carried out even when they are no longer capable of making or communicating their decisions. Every patient has the right to choose whether or not he or she wants to execute an advance directive.

Certain providers participating in the Medical Assistance Program must maintain written policies, procedures and materials concerning advance directives and give written information to all adults concerning their rights under State law to make decisions about their medical care.

Providers of Hospital, Long Term Care, Home Health Care, Personal Care, Hospice and Managed Care Organization (MCO) services must:

1. provide written information to all adult individuals concerning their rights under State law to:
    - make decisions concerning their medical care;
    - accept or refuse medical or surgical treatment; and
    - formulate advance directives, e.g., a living will or durable power of attorney for health care;

2. document in the individual's medical records whether or not the individual has executed an advance directive;

3. not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

4. ensure compliance with requirements of State law; and

5. provide (individually or with others) for education for staff and the community on issues concerning advance directives.

Providers are responsible for furnishing written information to all adult individuals at the time specified below:

- Hospitals – at the time an individual is admitted as an inpatient;
- Long Term Care facilities – when the individual is admitted as a resident;
- Home Health care or personal care service providers – before the individual comes under the care of the provider;
- Hospice program – at the time of initial receipt of hospice care by the individual from the program; and
- Managed Care Organizations – at the time of enrollment of the individual with the organization.

An individual may be admitted to a facility in a comatose or otherwise incapacitated state and be unable to receive information or articulate whether they have executed an advance directive. In this case, to the extent that a facility issues materials about policies and procedures to the families or to the surrogates or other concerned persons of the incapacitated patient in accordance with State law, it must also include the information concerning advance directives. This does not relieve the facility from its obligation to provide this information to the patient once the patient is no longer incapacitated.

When the patient or a relative, surrogate or other concerned or related individual presents the facility with a copy of the individual's advance directive, the facility must comply with the advance directive including recognition of the power of attorney, to the extent allowed under Sate law, unless the provider cannot as a matter of conscience implement such advance directive. If the provider cannot implement the advance direct, he or she must tell the patient or the patient's appropriate representative so that the patient can transfer to another provider. Absent contrary State law, if no one comes forward with a previously executed advance directive and the patients is incapacitated or otherwise unable to receive information or articulate whether they have executed an advance directive, the facility must note that the individuals was not able to receive information and was unable to communicate whether an advance directive existed.

LexisNexis®

LEXSEE 2000 U.S. APP. LEXIS 4112

Beta Steel Corporation, Petitioner, Cross-Respondent, v. National Labor Relations Board, Respondent, Cross-Petitioner.

Nos. 98-3658 and 98-4063

UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

2000 U.S. App. LEXIS 4112

December 3, 1999, Argued
March 14, 2000, Decided

NOTICE: [*1] RULES OF THE SEVENTH CIRCUIT COURT OF APPEALS MAY LIMIT CITATION TO UNPUBLISHED OPINIONS. PLEASE REFER TO THE RULES OF THE UNITED STATES COURT OF APPEALS FOR THIS CIRCUIT.

SUBSEQUENT HISTORY: Reported in Table Case Format at: *2000 U.S. App. LEXIS 13836*.

PRIOR HISTORY: On Petition for Review and Cross-Application for Enforcement of an Order of the National Labor Relations Board. No. 25-CA-25139.

DISPOSITION: Board's order enforced in full.

COUNSEL: For PATRICK M. LAWLOR, Petitioner - Appellant (98-3658): Edward W. Rausch, Parma, OH.

THOMAS P. GILMARTIN, JR., Petitioner - Appellant (98-4063), Pro se, Elkton, OH.

For KHELLEH KOHTAH, Respondent - Appellee (98-3658): Mark Joseph Zemba, Office of the Attorney General of Ohio, Cleveland, OH.

For UNITED STATES OF AMERICA, Respondent - Appellee (98-4063): Christian H. Stickan, Asst. U.S. Attorney, Office of the U.S. Attorney, Cleveland, OH.

JUDGES: Before Hon. Richard A. Posner, Chief Judge, Hon. John L. Coffey, Circuit Judge, Hon. Daniel A. Manion, Circuit Judge.

OPINION

ORDER

Beta Steel Corporation fired Dennis Holland in September 1996. Beta claims that it discharged Holland because he defrauded the company, while Holland asserts that it was because of his union activity. An administrative law judge and a National Labor Relations **[*2]** Board panel agreed with Holland, found that Beta violated the National Labor Relations Act, and ordered Beta to reinstate Holland with full back pay. Beta appeals, and we enforce the Board's order in full.

I.

Beta Steel Corporation ("Beta") processes steel at its facility in Portage, Indiana. Holland worked in Beta's shipping department from February 1993 to September 10, 1996, where he performed a variety of tasks. Each week, he attended the scales at the scalehouse for two days, worked as a "checker" to verify the accuracy of department data for one day, and drove a forklift to load large steel coils onto flatbed trucks for two days. The coils varied in size and weighed between 32,000 and 36,000 pounds.

In late 1995 or early 1996, Beta began using larger trucks to transfer a higher volume of steel coils from its mill to the Port of Indiana. With these larger trucks, Beta management discontinued the practice of securing the coils to the trucks with a steel chain. Holland complained to Beta management that discontinuing that practice was dangerous because unsecured coils could fall and seriously injure workers. As a member of Local 2038 of the International Longshoremen's **[*3]** Association (the "Union"), Holland also filed a Union grievance over the matter in February 1996. Beta temporarily reinstated the practice of chaining the coils but soon discontinued it.

In March 1996, an explosion at Beta's mill killed three employees and injured nine others. Holland was at the mill a few minutes earlier, but was in the scalehouse at the time of the explosion. He knew two of the workers who died, and had talked to one just a few minutes before the explosion. Afterwards, Beta offered counseling to employees, and kept on the payroll a number of them who were not ready to return to work for physical and/or psychological reasons. Holland was among 40 employees out of approximately 120 who did not return to work immediately.

Several weeks after the explosion, Holland began attending counseling sessions with Jeffrey Robinson, a licensed social worker retained by Beta. At the beginning of his counseling, Robinson advised Holland to continue to serve as a volunteer fireman in his home town of Lake Station, Indiana. Holland has served in that capacity since 1984, and regularly wore T-shirts and caps at Beta that indicated his volunteer service. And the vehicle that he drove **[*4]** to work had emergency lights and license plates indicating his participation with the volunteer fire department. In 1996 and at the time of the explosion, Holland was the fire department's safety officer, drove a fire truck and ambulance, and assured that all the firemen wore proper safety equipment. This was not gainful employment, as he received only nominal compensation for his service. Counselor Robinson encouraged Holland to continue responding to fire calls because he believed that such activity would be helpful psychologially and would hasten Holland's return to work with Beta.

Holland did return to work on May 20, 1996, but only for light duty because he was psychologically uncomfortable driving the forklift at the speeds that his job required. He provided Beta with a note from his physician, William Forgey, M.D., that affirmed his work restriction. In early August 1996, he obtained his doctor's release and resumed driving forklifts.

In late July or early August, Holland became the chairman of the safety committee for the shipping department. Beta and the Union established this and similar committees after the March 1996 explosion, and the collective bargaining agreement **[*5]** ("CBA") mandated them. As chairman, Holland complained again to James Hunt, Beta's safety director, about Beta's failure to chain the steel coils to the trucks. Beta supervisor Lee Spitka responded that the chains were unnecessary because 4 x 4 blocks of wood adequately blocked the coils.

On August 27, 1996, Beta's vice-president, Toli Fliakos, summoned Holland to his office to tell him that he just learned that Holland was answering fire calls while he was off work from Beta, and while on light duty. Fliakos said that he considered this an abuse of Beta's employee accommodations, but Holland responded that he never hid his work as a volunteer fireman, and that no one from Beta asked him about it. Fliakos concluded that he would not discipline Holland, but asserted that Beta was not pleased with his conduct.

On September 10, 1996, Mike Tsampis, one of Holland's co-workers, asked Holland for a safety suggestion form, which he provided. Tsampis completed the form to suggest that the trucks should have one chain that secures each steel coil before the trucks leave the mill. As the safety committee chairman, Holland co-signed the form and submitted it to Spitka. One hour later, Fliakos **[*6]** called Holland to his office to suspend him, subject to discharge, for answering fire calls while off work and on restricted duty.

A few days later, Holland and Union officials met with management in a grievance proceeding. Holland presented management with Robinson's letter that confirmed that he encouraged Holland to continue his volunteer fire fighting service because it would help him to prepare for his return to work at Beta. Holland also reiterated that his service was not gainful employment. But Beta confirmed its decision to terminate Holland, and he filed an unfair labor practice charge with the National Labor Relations Board ("NLRB" or the "Board").

Before the NLRB hearing, Beta's counsel alleged that Board agent Andrew Stites made several promises that he would provide Beta with the Board's lists of

witnesses and exhibits if Beta allowed him to take the affidavits of its personnel. Counsel obliged and Stites obtained the affidavits, but never provided Beta with the Board's information. In response to this alleged broken promise, Beta sought injunctive relief in the United States District Court in Hammond, Indiana to stay the hearing, but this effort failed. Later, on October 21, 1997, during **[*7]** a prehearing conference call with the Administrative Law Judge ("ALJ") and the NLRB's General Counsel, Beta's counsel asked the ALJ to order the General Counsel to provide the Board's lists of witnesses and exhibits according to Beta's deal with Stites. The ALJ concluded that pursuant to *Section 102.118* of the National Labor Relations Act ("NLRA" or "the Act") which prohibited such pre-trial disclosure, the ALJ lacked the authority to order the Board to disclose the information. *29 C.F.R. § 102.118*. The ALJ also concluded that Stites, in his capacity as agent for the Board, had no authority to make such representations, and that Beta's reliance on them was not reasonable in light of the NLRA regulation. The ALJ then scheduled the hearing for October 27, 1996.

On October 24, Beta's counsel initiated another conference call to revisit his allegations about Stites's misrepresentations. The ALJ allegedly offered to leave the record open, after the Board's witnesses testified, and to reconvene the hearing so that Beta could adequately address the testimony. [1] According to the ALJ, Beta's counsel did not accept that offer, did not seek a continuance of the hearing, and then failed to **[*8]** attend the hearing. The ALJ proceeded with the hearing in Beta's absence, and concluded that Beta violated the NLRA by discharging Holland for engaging in the protected concerted activity of filing a safety complaint. An NLRB panel adopted the ALJ's decision. Beta appeals, claiming that the NLRB violated its due process rights when Stites lied to Beta's counsel to obtain the affidavits of Beta's personnel, and that the NLRB's decision lacks the support of substantial evidence.

1 Beta's counsel asserts, however, that the ALJ never communicated the offer to him.

II.

Beta's first argument is that the Board violated Beta's due process rights when Stites, the Board's agent, lied to Beta, causing it to waive its right to refrain from prehearing discovery. According to Beta, Stites's promises "expressly waived" the NLRB's "general policy" against pre-hearing discovery.

The restriction against pre-hearing discovery is not merely a policy, but a regulation that reads:

> No present or former Regional Director, **[*9]** field examiner, administrative law judge, attorney, specially designated agent, General Counsel, Member of the Board or other officer or employee of the Agency shall produce or present any files, documents, reports, memoranda, or records of the Board or of the General Counsel, whether in response to a subpoena duces tecum or otherwise . . . . [2]

29 C.F.R. § 102.118(a)(1). This court has affirmed this regulation because it "provides necessary protection to witnesses who will be testifying against an entity which controls their livelihood." *NLRB v. Champion Laboratories, Inc., 99 F.3d 223, 226 (7th Cir. 1996)*. Moreover, the "general rule is that 'those who deal with the Government are expected to know the law and may not rely on the conduct of Government agents contrary to law.'" *Kelley v. NLRB, 79 F.3d 1238, 1249 (1st Cir. 1996)* (*quoting Heckler v. Community Health Services, 467 U.S. 51, 63, 81 L. Ed. 2d 42, 104 S. Ct. 2218 (1984)*). And "it is established law that the Board is not bound by advice given to employers by Board agents, especially when employee rights are violated pursuant to that advice." *Ivaldi v. NLRB, 48 F.3d 444, 451 (9th Cir. 1995)*. **[*10]**

2 While this regulation does allow Board agents to produce documents if they obtain the written permission of the Board or the General Counsel, Stites never obtained such permission in this case. *29 C.F.R. § 102.118(a)(1)*.

Beta should have known that the restriction against prehearing discovery is a regulation, not just a "general policy," and that a Board agent lacks the authority to waive the regulatory restriction by promising to make a deal to engage in such discovery. [3] Since Beta's counsel must know the law, his reliance on the Board agent's promises to the contrary was not reasonable. *See Kelley, 79 F.3d at 1250* (attorney's reliance on Board agent's misleading and incomplete statement of Board procedure was not reasonable since the agent's information "is not nearly as reliable as simply looking up the text of a

regulation."). And finally, the ALJ provided Beta with due process: an opportunity to attend the hearing and present a defense.

> 3 At oral argument, the NLRB could not confirm or deny that Stites made the alleged misrepresentations. It seems clear, however, that the Board did have unusual access to Beta personnel to obtain affidavits. We strongly admonish the NLRB to investigate this matter to ensure that, if its agent did lull counsel for Beta into giving inappropriate access, it does not happen again.

[*11] Beta also contends that there is no substantial evidence to support the NLRB's decision that Beta violated Sections 7, 8(a)(1) and 8(a)(3) of the NLRA. We uphold the Board's factual findings if they are supported by substantial evidence in the record as a whole, and its legal conclusions if they have a reasonable basis in the law. *NLRB v. Joy Recovery Technology Corp., 134 F.3d 1307, 1312 (7th Cir. 1998)*. Substantial evidence "means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Roadmaster Corp. v. NLRB, 874 F.2d 448, 452 (7th Cir. 1989)*.

Beta argues that there is no evidence that Holland engaged in a protected concerted activity pursuant to § 7 of the Act. Section 7 guarantees employees the right to engage in "concerted activities for the purpose of collective bargaining or other mutual aid or protection." *29 U.S.C. § 157*. Section 8(a)(1) prohibits employers from interfering with employees who exercise their Section 7 rights. *29 U.S.C. § 158(a)(1)*; *Roadmaster, 874 F.2d at 452*. And "to further protect employees engaged in protected concerted **[*12]** activity under § 7, the NLRA [Section 8(a)(3)] also makes it an unfair labor practice for an employer to encourage or discourage membership in a labor organization by discriminating in regard to hire or tenure of employment." *Roadmaster, 874 F.2d at 452*; *29 U.S.C. § 158(a)(3)*. To prove that Beta violated Section 8(a)(3), the General Counsel must prove by a preponderance of the evidence that: (1) Beta knew that Holland was a union member; (2) Holland engaged in a protected concerted activity; (3) Beta took an employment action adverse to Holland; and (4) Holland's protected concerted activity was a motivating factor in Beta's decision. *Joy Recovery, 134 F.3d at 1314*; *E & L Transport Co. v. NLRB, 85 F.3d 1258, 1271 (7th Cir. 1996)*. If the General Counsel satisfies this burden, Beta can still avoid liability by proving by a preponderance of the evidence that it discharged Holland for legitimate business reasons. *Joy Recovery, 134 F.3d at 1314*.

Beta claims that there is no evidence that Holland engaged in a protected concerted activity because he never submitted a safety complaint form, but merely **[*13]** accepted it from Tsampis and delivered it to management as chairman of the safety committee. According to Beta, since it appointed Holland the committee chairman, he delivered the form at Beta's request, and thus this delivery could not constitute Union activity. The Board found that Holland engaged in Union activity because he attempted "to enforce the safety and health provisions of the [CBA] with regard to chaining down the coils."

"Whether an employee's concerted activity remains under the protection of § 7 depends on the facts of each particular case." *Roadmaster, 874 F.2d at 452*. And we will uphold the Board's determination regarding an employee's concerted activity "so long as it is not illogical or arbitrary." *Id.* In this case, Holland served as the chairman of an employee safety committee that Beta and the Union created according to the CBA. Although he did not complete Tsampis's safety form, he co-signed it and delivered it to Beta management according to his duties as the committee chairman. Holland acted on behalf of the employees in the shipping department to identify and resolve a potential safety hazard, and thus to promote the employees' "mutual **[*14]** aid or protection." *29 U.S.C. § 157*. Therefore, he engaged in a protected concerted activity under § 7. *See id.* ("Naturally, this [§ 7] protection extends to a union steward or official who aids another employee in filing a grievance."); *Cormier v. Simplex Technologies, Inc., 1999 U.S. Dist. LEXIS 21516*, No. 98-500, 1999 WL 628120, at *5 (D.N.H. March 4, 1999) (As a member of the safety committee, employee "was clearly acting on behalf of other employees, with their knowledge and consent. These [safety] complaints clearly satisfy the mutual aid and protection clause [of § 7] as well."). Therefore, the Board's finding that Holland engaged in a protected concerted activity was not illogical or arbitrary.

Lastly, Beta asserts that even if Holland engaged in protected concerted activity, Beta discharged him because he defrauded the company when he responded to fire calls while on paid leave and light duty. The Board

determined that Holland's testimony about his August 27, 1996 meeting with Fliakos was credible, [4] and concluded that since Fliakos knew about Holland's fire-fighting service, but did not act on it until an hour after the delivery of the safety form **[*15]** on September 10, 1996, Holland's union activity was the motivating factor in Beta's decision, not his service with the fire department.

> 4 There are no "extraordinary circumstances" that compel us to overturn the Board's credibility determinations. *NLRB v. Augusta Bakery Corp., 957 F.2d 1467, 1477 (7th Cir. 1992)*.

The record provides substantial evidence to support the Board's determination that Holland's protected concerted activity (not Beta's legitimate business reason) motivated Beta's decision to terminate him. *Joy Recovery, 134 F.3d at 1314*. The Board may rely on circumstantial evidence to assess the employer's motive. *NLRB v. Dorothy Shamrock Coal Co., 833 F.2d 1263, 1267 (7th Cir. 1987)*. Holland's credible testimony shows that while Fliakos knew about Holland's service with the volunteer fire department, Fliakos waited until weeks later to discharge him right after he delivered a safety complaint. When Holland had made the same complaints in the past, **[*16]** he encountered Beta's opposition. This indicates that Beta management would not welcome yet another such complaint, especially one co-signed by Holland as the chairman of the safety committee. Additionally, the Board's conclusion that the timing of Holland's discharge "strongly suggests discrimination" is a valid inference. "Timing alone may suggest anti-union animus as a motivating factor in an employer's action," and an employer's timing may provide the "strongest support" of an unfair labor practice. *NLRB v. Rain-Ware, Inc., 732 F.2d 1349, 1354 (7th Cir. 1984)*. Therefore, the record provides enough evidence to convince reasonable minds that Beta violated the NLRA when it fired Holland for his protected concerted activity. [5] We enforce the Board's order in full.

> 5 Had Beta's counsel accepted the alleged offer to submit documents or other evidence to address the Board's testimony, or had appeared at the hearing, a different result was possible. But the record as it stands is sufficient to establish the violation.

[*17]

Department of Justice

FOR IMMEDIATE RELEASE
Wednesday, September 2, 2009
WWW.USDOJ.GOV

AAG
(202) 514-2007
TDD (202) 514-1888

Justice Department Announces Largest Health Care Fraud Settlement in Its History

Pfizer to Pay $2.3 Billion for Fraudulent Marketing

WASHINGTON – American pharmaceutical giant Pfizer Inc. and its subsidiary Pharmacia & Upjohn Company Inc. (hereinafter together "Pfizer") have agreed to pay $2.3 billion, the largest health care fraud settlement in the history of the Department of Justice, to resolve criminal and civil liability arising from the illegal promotion of certain pharmaceutical products, the Justice Department announced today.

Pharmacia & Upjohn Company has agreed to plead guilty to a felony violation of the Food, Drug and Cosmetic Act for misbranding Bextra with the intent to defraud or mislead. Bextra is an anti-inflammatory drug that Pfizer pulled from the market in 2005. Under the provisions of the Food, Drug and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to FDA. Once approved, the drug may not be marketed or promoted for so-called "off-label" uses – *i.e.*, any use not specified in an application and approved by FDA. Pfizer promoted the sale of Bextra for several uses and dosages that the FDA specifically declined to approve due to safety concerns. The company will pay a criminal fine of $1.195 billion, the largest criminal fine ever imposed in the United States for any matter. Pharmacia & Upjohn will also forfeit $105 million, for a total criminal resolution of $1.3 billion.

In addition, Pfizer has agreed to pay $1 billion to resolve allegations under the civil False Claims Act that the company illegally promoted four drugs – Bextra; Geodon, an anti-psychotic drug; Zyvox, an antibiotic; and Lyrica, an anti-epileptic drug – and caused false claims to be submitted to government health care programs for uses that were not medically accepted indications and therefore not covered by those programs. The civil settlement also resolves allegations that Pfizer paid kickbacks to health care providers to induce them to prescribe these, as well as other, drugs. The federal share of the civil settlement is $668,514,830 and the state Medicaid share of the civil settlement is $331,485,170. This is the largest civil fraud settlement in history against a pharmaceutical company.

As part of the settlement, Pfizer also has agreed to enter into an expansive corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services. That agreement provides for procedures and reviews to be put in place to avoid and promptly detect conduct similar to that which gave rise to this matter.

Whistleblower lawsuits filed under the *qui tam* provisions of the False Claims Act that are pending in the District of Massachusetts, the Eastern District of Pennsylvania and the Eastern District of Kentucky triggered this investigation. As a part of today's resolution, six whistleblowers will receive payments totaling more than $102 million from the federal share of the civil recovery.

The U.S. Attorney's offices for the District of Massachusetts, the Eastern District of Pennsylvania, and the Eastern District of Kentucky, and the Civil Division of the Department of Justice handled these cases. The U.S. Attorney's Office for the District of Massachusetts led the criminal investigation of Bextra. The investigation was conducted by the Office of Inspector General for the Department of Health and Human Services (HHS), the FBI, the Defense Criminal Investigative Service (DCIS), the Office of Criminal Investigations for the Food and Drug Administration (FDA), the Veterans' Administration's (VA) Office of Criminal Investigations, the Office of the Inspector General for the Office of Personnel Management (OPM), the Office of the Inspector General for the United States Postal Service (USPS), the National Association of Medicaid Fraud Control Units and the offices of various state Attorneys General.

"Today's landmark settlement is an example of the Department of Justice's ongoing and intensive efforts to protect the American public and recover funds for the federal treasury and the public from those who seek to earn a profit through fraud. It shows one of the many ways in which federal government, in partnership with its state and local allies, can help the American people at a time when budgets are tight and health care costs are increasing," said Associate Attorney General Tom Perrelli. "This settlement is a testament to the type of broad, coordinated effort among federal agencies and with our state and local partners that is at the core of the Department of Justice's approach to law enforcement."

"This historic settlement will return nearly $1 billion to Medicare, Medicaid, and other government insurance programs, securing their future for the Americans who depend on these programs," said Kathleen Sebelius, Secretary of Department of Health and Human Services**.** "The Department of Health and Human Services will continue to seek opportunities to work with its government partners to prosecute fraud wherever we can find it. But we will also look for new ways to prevent fraud before it happens. Health care is too important to let a single dollar go to waste."

"Illegal conduct and fraud by pharmaceutical companies puts the public health at risk, corrupts medical decisions by health care providers, and costs the government billions of dollars," said Tony West, Assistant Attorney General for the Civil Division. "This civil settlement and plea agreement by Pfizer represent yet another example of what penalties will be faced when a pharmaceutical company puts profits ahead of patient welfare."

"The size and seriousness of this resolution, including the huge criminal fine of $1.3 billion, reflect the seriousness and scope of Pfizer's crimes," said Mike Loucks, acting U.S. Attorney for the District of Massachusetts. "Pfizer violated the law over an extensive time period. Furthermore, at the very same time Pfizer was in our office negotiating and resolving the allegations of criminal conduct by its then newly acquired subsidiary, Warner-Lambert, Pfizer was itself in its other operations violating those very same laws. Today's enormous fine demonstrates that such blatant and continued disregard of the law will not be tolerated."

"Although these types of investigations are often long and complicated and require many resources to achieve positive results, the FBI will not be deterred from continuing to ensure that pharmaceutical companies conduct business in a lawful manner," said Kevin Perkins, FBI Assistant Director, Criminal Investigative Division.

"This resolution protects the FDA in its vital mission of ensuring that drugs are safe and effective. When manufacturers undermine the FDA's rules, they interfere with a doctor's judgment and can put patient health at risk," commented Michael L. Levy, U.S. Attorney for the Eastern District of Pennsylvania. "The public trusts companies to market their drugs for uses that FDA has approved, and trusts that doctors are using independent judgment. Federal health dollars should only be spent on treatment decisions untainted by misinformation from manufacturers concerned with the bottom line."

"This settlement demonstrates the ongoing efforts to pursue violations of the False Claims Act and recover taxpayer dollars for the Medicare and Medicaid programs," noted Jim Zerhusen, U.S. Attorney for the Eastern District of Kentucky.

"This historic settlement emphasizes the government's commitment to corporate and individual accountability and to transparency throughout the pharmaceutical industry," said Daniel R. Levinson, Inspector General of the United States Department of Health and Human Services. "The corporate integrity agreement requires senior Pfizer executives and board members to complete annual compliance certifications and opens Pfizer to more public scrutiny by requiring it to make detailed disclosures on its Web site. We expect this agreement to increase integrity in the marketing of pharmaceuticals."

"The off-label promotion of pharmaceutical drugs by Pfizer significantly impacted the integrity of TRICARE, the Department of Defense's healthcare system," said Sharon Woods, Director, Defense Criminal Investigative Service. "This illegal activity increases patients' costs, threatens their safety and negatively affects the delivery of healthcare services to the over nine million military members, retirees and their families who rely on this system. Today's charges and settlement demonstrate the ongoing commitment of the Defense Criminal Investigative Service and its law enforcement partners to investigate and prosecute those that abuse the government's healthcare programs at the expense of the taxpayers and patients."

"Federal employees deserve health care providers and suppliers, including drug manufacturers, that meet the highest standards of ethical and professional behavior," said Patrick E. McFarland, Inspector General of the U.S.

Office of Personnel Management. "Today's settlement reminds the pharmaceutical industry that it must observe those standards and reflects the commitment of federal law enforcement organizations to pursue improper and illegal conduct that places health care consumers at risk."

"Health care fraud has a significant financial impact on the Postal Service. This case alone impacted more than 10,000 postal employees on workers' compensation who were treated with these drugs," said Joseph Finn, Special Agent in Charge for the Postal Service's Office of Inspector General. "Last year the Postal Service paid more than $1 billion in workers' compensation benefits to postal employees injured on the job."

###

09-900

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA *ex rel.* CHRISTOPHER R. GOBBLE, *et al.*,	**Civil Action No. 03-10395-NMG**
Plaintiff,	
v.	
FOREST LABORATORIES, INC., and FOREST PHARMACEUTICALS, INC.,	**FILED UNDER SEAL**
Defendants.	
UNITED STATES OF AMERICA *ex rel.* JOSEPH PIACENTILE, *et al.*,	**Civil Action No. 05-10201-NMG**
Plaintiff,	
v.	
FOREST LABORATORIES, INC.,	
Defendant.	

UNITED STATES' COMPLAINT IN INTERVENTION

The United States brings this action to recover losses from false claims submitted to federal health care programs as a result of the sustained fraudulent course of conduct of the defendants, Forest Laboratories, Inc. ("Forest Labs"), and Forest Pharmaceuticals, Inc. ("Forest Pharmaceuticals") (collectively, "Forest"). Over the course of more than half a decade, Forest illegally marketed two related antidepressant drugs, Celexa and Lexapro, for off-label use in pediatric patients when both drugs had been approved only for adult use. During much of that

time, Forest misled physicians by promoting the results of a positive study on pediatric use of Celexa while failing to disclose the results of a contemporaneous negative study for the same pediatric use. Forest also illegally paid kickbacks to physicians to induce them to prescribe the drugs. By knowingly and actively promoting these antidepressants for off-label pediatric use without disclosing the results of the negative pediatric study and by paying kickbacks, Forest caused false claims to be submitted to federal health care programs in violation of the False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq.*

I. NATURE OF ACTION

1. The United States brings this action to recover treble damages and civil penalties under the FCA and to recover damages and other monetary relief under the common law or equitable theory of unjust enrichment.

2. The United States bases its claims on Forest causing the submission of false or fraudulent claims to federal health care programs in violation of 31 U.S.C. § 3729(a)(1).

3. Within the time frames detailed below, Forest engaged in a fraudulent scheme to market and promote Celexa (citalopram) and Lexapro (escitalopram) off-label to treat depression and other psychiatric conditions in pediatric patients. Forest did so even though the Food and Drug Administration ("FDA") had not approved the drugs as safe and effective for any use in the pediatric population. In the case of Celexa, the FDA had specifically denied approval for any pediatric use.

4. In furtherance of its off-label marketing scheme, Forest disseminated and caused others to disseminate false and misleading information to doctors and the public about the safety

and efficacy of Celexa and Lexapro in treating pediatric patients. At the same time that Forest was actively touting pediatric use of the drugs, the company failed to disclose the negative results of a large, placebo-controlled study that found Celexa no more effective than placebo for pediatric use and in which more patients taking Celexa attempted suicide or reported suicidal ideation than those taking only placebo. The negative data that Forest failed to disclose was among the data later considered by the FDA when mandating that Forest add a "black box" warning to both the Celexa and Lexapro labels for pediatric use.

5. In addition to its illegal off-label marketing scheme, Forest sought to induce physicians and others to prescribe Celexa and Lexapro by providing them with various forms of illegal remuneration, including cash payments disguised as grants or consulting fees, expensive meals and lavish entertainment, and other valuable goods and services, all in violation of the federal anti-kickback statute, 42 U.S.C. § 3120a-7b(b) ("AKS").

6. As the direct, proximate, and foreseeable result of Forest's fraudulent course of conduct, as set forth above and herein, Forest caused thousands of false or fraudulent claims to be submitted to the federal health care programs for Celexa and Lexapro prescriptions that were not covered for off-label pediatric use and/or were ineligible for payment as a result of illegal kickbacks.

II. JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1345.

8. This Court may exercise personal jurisdiction over Forest pursuant to 31 U.S.C.

§ 3732(a) and because Forest transacts business in the District of Massachusetts.

9. Venue is proper in the District of Massachusetts under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because Forest has transacted business in this District.

III. PARTIES

10. The United States brings this action on behalf of the Department of Health and Human Services ("HHS"); the Centers for Medicare & Medicaid Services ("CMS") (formerly known as the Health Care Financing Administration), which administers the Medicaid program; and the Department of Defense, which administers the TRICARE/CHAMPUS program ("TRICARE") (collectively, "federal health care programs").

11. Relator Christopher R. Gobble is a resident of Virginia and a former employee of Forest. In March 2003, Mr. Gobble filed an action alleging violations of the FCA on behalf of himself and the United States Government pursuant to the *qui tam* provisions of the FCA, 31 U.S.C. § 3730(b)(1).

12. Relator Joseph Piacentile is a resident of New Jersey. On August 20, 2001, Mr. Piacentile filed an action alleging violations of the FCA on behalf of himself and the United States Government pursuant to the *qui tam* provisions of the FCA, 31 U.S.C. § 3730(b)(1).

13. Defendant Forest Labs is a pharmaceutical company organized under the laws of Delaware with its principal place of business in New York, New York. Forest Labs has a license from H. Lundbeck A/S ("Lundbeck"), a Danish company, to promote and sell Celexa and Lexapro in the United States.

14. Defendant Forest Pharmaceuticals is a wholly owned subsidiary of Forest Labs

with its principal place of business in St. Louis, Missouri. Forest Pharmaceuticals manufactures, distributes, and sells Forest prescription products in the United States.

IV. THE LAW

A. The False Claims Act

15. The FCA, 31 U.S.C. §§ 3729-33, provides for the award of treble damages and civil penalties for, *inter alia*, knowingly causing the submission of false or fraudulent claims for payment to the United States Government. 31 U.S.C. § 3729(a)(1).

16. The FCA provides, in pertinent part, that:

> (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
>
> * * *
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person . . . .
>
> (b) For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

31 U.S.C. § 3729.

17. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the FCA civil penalties were adjusted to $5,500 to $11,000 for

violations occurring on or after September 29, 1999.

B. The Federal Anti-Kickback Statute

18. The federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that remuneration and gifts given to those who can influence health care decisions corrupts medical decision-making and could result in the provision of goods and services that are 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 statute was enacted in 1972; Congress strengthened it in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, 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.

19. The AKS prohibits any person or entity from offering, making, or accepting payment to induce or reward any person for referring, recommending, or arranging for the purchase of any item for which payment may be made in whole or in part by a federal health care program. In pertinent part, the statute provides:

> (b) Illegal remuneration
>
> * * *
>
> (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 a 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.

42 U.S.C. § 1320a-7b(b).

20. Under the AKS, drug companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to prescribe drugs for which payment may be made by federal health care programs.

21. The AKS not only prohibits outright bribes, but also prohibits any remuneration by a drug company to a physician that has as one of its purposes inducement of the physician to write prescriptions for the company's pharmaceutical products.

V. THE FEDERAL HEALTH CARE PROGRAMS

A. The Medicaid Program

22. The Medicaid program is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled. Each state administers a state Medicaid program and receives funding from the federal government, known as federal financial participation, based upon a formula set forth in the federal Medicaid statute.

23. Before the beginning of each calendar quarter, each state submits to CMS an

estimate of its Medicaid funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding the state will be permitted to draw down as the state actually incurs expenditures during the quarter (for example, as actual provider claims are presented for payment). After the end of each quarter, the state then submits to CMS a final expenditure report, which provides the basis for adjustment to quarterly federal funding (to reconcile the estimated expenditures to actual expenditures).

24. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. 42 U.S.C. § 1396a.

25. The federal Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A).

26. While federal drug coverage is an optional benefit available to the states, most states provide coverage for prescription drugs that meet the definition of a covered outpatient drug, which is defined in the federal Medicaid Rebate Statute, 42 U.S.C. § 1396r-8(k)(2).

27. The Medicaid Rebate Statute generally prohibits federal financial participation for a covered outpatient drug unless there is a rebate agreement in effect with the manufacturer for that drug. Once a drug manufacturer has entered into a rebate agreement for a covered outpatient drug, a state is generally required to cover that drug under the state plan unless "the prescribed use is not for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B)(i).

28. The Medicaid Rebate Statute defines "medically accepted indication" as any FDA approved use or a use that is "supported by one or more citations included or approved for

inclusion in any of the compendia" set forth in the statute. 42 U.S.C. § 1396r-8(k)(6).

29. A drug does not generally meet the definition of a "covered outpatient drug" if it is being prescribed for a use that is neither FDA-approved nor supported by a citation included or approved for inclusion in the compendia. 42 U.S.C. §§ 1396r-8(k)(2)(A), (k)(3).

30. Thus, even if a drug is FDA-approved for a certain indication, Medicaid ordinarily does not cover off-label uses that do not qualify as medically accepted indications. Many state Medicaid programs prohibit covering such uses. *See, e.g.*, 40-850-026 DEL. CODE REGS. § 3.5.4.1 (2008); IND. CODE § 12-15-35-4.5 (2008); N.J. ADMIN. CODE § 83C-1.14(1) (2008); N.M. CODE R. § 8.325.4 (2008).

B. The TRICARE Program

31. TRICARE, formerly known as CHAMPUS, is a managed health care program established by the Department of Defense. 10 U.S.C. §§ 1071-1110. TRICARE provides health care benefits to eligible beneficiaries, which include, among others, active duty service members, retired service members, and their dependents.

32. The regulatory authority establishing the TRICARE program does not cover drugs not approved by the FDA. *See* 32 C.F.R. § 199.4(g)(15)(i)(A).

33. TRICARE does not cover drugs used for off-label indications unless such off-label use is proven medically necessary and safe and effective by medical literature, national organizations, or technology assessment bodies. *See* 32 C.F.R. §199.4(g)(15)(i)(A)(Note). TRICARE will not knowingly provide reimbursement for off-label use if the prescriptions result from illegal off-label marketing.

VI. FOREST'S SCHEME

A. The Celexa And Lexapro Labels

34. Celexa and Lexapro are closely-related selective serotonin reuptake inhibitor ("SSRIs") drugs. Lundbeck developed both Celexa and Lexapro, which contains the active agent in Celexa, and subsequently licensed both drugs to Forest for marketing in the United States. Forest began selling Celexa in 1998. In 2002, with Celexa soon due to face generic competition, Forest began selling Lexapro.

1. The FDA Has Not Approved Celexa Or Lexapro For Pediatric Use.

35. In 1998, the FDA approved Celexa for the treatment of adult depression. The FDA never approved Celexa for treatment of any conditions other than adult depression, or for any pediatric use.

36. In 2002, the FDA approved Lexapro for the treatment of adult depression. In 2003, Lexapro received approval for treatment of Generalized Anxiety Disorder ("GAD") in adults. Lexapro has not been approved for any other conditions and was not approved for pediatric use.

37. The use of Celexa and Lexapro in pediatric patients is not supported by a citation included or approved for inclusion in any of the compendia. The use of Celexa and Lexapro in pediatric patients is not a "medically accepted" indication for those drugs.

38. If a manufacturer conducts pediatric clinical studies on a drug, a manufacturer may obtain an additional six months of patent exclusivity for the previously-approved, on-label

indications for that particular drug subject to certain FDA requirements. 21 U.S.C. § 355a. In such circumstances, the FDA issues a "Written Request" that details the studies that should be performed. 21 U.S.C. § 355a(c)(2)(A).

39. In August 1998, Forest submitted a "Proposed Pediatric Study Request for Celexa." On April 28, 1999, the FDA issued a Written Request to Forest to conduct "two independent, adequate and well-controlled clinical trials in pediatric depression" for Celexa.

40. On September 24, 1999, Forest submitted to the FDA protocols for two pediatric studies: 1) a double-blind, placebo-controlled pediatric study being conducted in Europe by Lundbeck (the "Lundbeck study"); and 2) a double-blind, placebo-controlled pediatric study to be conducted in the United States by Forest through University of Texas child psychiatrist Karen Wagner (the "Wagner study").

41. In mid-2001, the Wagner and Lundbeck studies were unblinded and their results were disseminated to senior Forest executives. The Wagner study was positive, *i.e.*, it indicated that Celexa was more effective than placebo in treating pediatric patients suffering from depression, but the Lundbeck study was negative, *i.e.*, it did not show Celexa to be any more effective than placebo in treating pediatric depression. Furthermore, in the Lundbeck study, 14 of the patients taking Celexa attempted suicide or reported suicidal ideation (*i.e.*, contemplation of suicide) compared to only 5 patients taking placebo. Under one statistical test, this result was "significant," and, under another statistical test, it was "borderline significant."

42. On April 18, 2002, Forest submitted the results of both the Lundbeck and Wagner studies to the FDA in support of requests for both a six-month extension of patent exclusivity

and a pediatric indication for Celexa. Forest's submission to the FDA was not public.

43. On July 15, 2002, the FDA granted Celexa six additional months of patent exclusivity for the on-label use of treating depression in adults.

44. On September 23, 2002, the FDA denied Forest's request for a pediatric indication for Celexa. The FDA concluded that the Lundbeck study "is a clearly negative study that provides no support for the efficacy of citalopram in pediatric patients with [major depressive disorder]."

2. The FDA-Mandated Black Box Warnings On The Celexa And Lexapro Labels

45. On March 22, 2004, the FDA issued a public health advisory requesting that certain SSRI manufacturers, including Forest, change the labels on their SSRI drugs to include "a [w]arning statement that recommends close observation of adult and pediatric patients treated with these agents for worsening depression or the emergence of suicidality."

46. Later that year, the FDA directed the SSRI manufacturers, including Forest, to include on their labels a black box warning and expanded statements to alert physicians about the potential for increased risk of suicidality in children and adolescents taking SSRIs. The black box warning specifically stated that "[a]ntidepressants *increased the risk* of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders." (Emphasis added). In addition, the FDA required SSRI manufacturers to state, in relevant part, that:

> The risk of suicidality for these drugs was identified in a combined analysis of short-term (up to 4 months) placebo-controlled trials of nine antidepressant drugs, including the selective serotonin reuptake inhibitors (SSRIs) and others, in

children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders. A total of 24 trials involving over 4400 patients were included. The analysis showed a greater risk of suicidality during the first few months of treatment in those receiving antidepressants.

47. The Lundbeck study on pediatric use of Celexa was one of the 24 trials considered by the FDA in mandating this warning.

48. Forest revised the Celexa and Lexapro labels in early 2005 to include the required black box warning and to state under each label's "Pediatric Use" subheading that "[s]afety and effectiveness in the pediatric population have not been established (see BOX WARNING and WARNINGS-Clinical Worsening and Suicide Risk)." The Celexa label further stated that "[t]wo placebo-controlled trials in 407 pediatric patients with MDD have been conducted with Celexa, and the data were not sufficient to support a claim for use in pediatric patients," while the Lexapro label stated that "[o]ne placebo-controlled trial in 264 pediatric patients with MDD has been conducted with Lexapro, and the data were not sufficient to support a claim for use in pediatric patients."

49. In 2007, the Celexa and Lexapro labels were again modified to state that, after evaluating the pooled analyses of placebo-controlled SSRI trials in children and adolescents and of trials in adults, "[t]here was considerable variation in risk of suicidality among drugs, but a tendency toward an increase in the younger patients for almost all drugs studied."

50. To date, Forest has not obtained FDA approval for a pediatric indication for Celexa or Lexapro. Both the Celexa and Lexapro labels currently include black box warnings explicitly indicating that the safety and efficacy of the drugs in the pediatric population have not

been established.

B. Forest's Dissemination Of Half Truths As A Result Of Its Failure To Disclose The Results Of The Negative Lundbeck Study

51. Although Forest submitted the Lundbeck study to the FDA in 2002 in order to seek a six-month extension of patent exclusivity for Celexa (which Forest later valued at $485 million), Forest failed otherwise to disclose the negative study beyond a small group of its senior executives. At the same time, Forest aggressively promoted the Wagner study, thereby relaying the false impression that the only available pediatric data on Celexa was positive.

52. Although the Forest senior executives learned about the negative Lundbeck results in mid-2001, Forest failed for the next three years to disclose that negative data to, among others: its thousands of sales representatives who were detailing pediatric specialists; pediatric specialists whom it hired to give promotional speeches on Celexa and Lexapro; the members of its Executive Advisory Board of leading psychiatrists upon whom it ostensibly relied for advice concerning new data and upon whom it also relied to convey information to others; its own Professional Affairs Department, which it charged with disseminating "balanced" information in response to physician requests for available data on Forest drugs; or even its own pediatric researchers such as Dr. Wagner.

53. During this same time period, Forest took aggressive steps to publicize the positive results of the Wagner study. On August 27, 2001, Forest presented the Wagner study results to its Executive Advisory Board without making any mention of the contemporaneous negative Lundbeck results. Forest thereafter arranged for Dr. Wagner to present a poster summary of the Wagner study to various professional groups, including the American Psychiatric

Association, the American College of Neuropsychopharmacology, and the Collegium Internationale Neuro-Psychopharmalogicum. In conjunction with these presentations, Forest coordinated the "placement" of news stories about the positive Wagner data in numerous national and local media outlets.

54. Over the course of 2002, Forest arranged for Dr. Wagner to give promotional presentations on the pediatric use of Celexa and to serve as the chair of a seven-city Continuing Medical Education ("CME") program on treating pediatric depression. Forest also sponsored 20 CME teleconferences that addressed the Wagner study results.

55. Forest's simultaneous failure to disclose the negative Lundbeck study results and wide publication of the positive Wagner study results caused Forest and its consultants to make false or misleading statements. For example, because not even Dr. Wagner was aware of the negative Lundbeck data, she never discussed that data in her many Forest-sponsored talks addressing the pediatric use of Celexa and Lexapro. Her slide presentations addressed negative studies on pediatric use of other SSRIs, but falsely indicated that there were no negative studies on the pediatric use of Celexa.

56. Forest's failure to disclose the negative Lundbeck results to the members of Forest's Executive Advisory Board caused those members to make false or misleading statements in promotional teleconferences on Celexa and Lexapro. During the teleconferences, which were targeted to large numbers of physicians across the country, the Forest Executive Advisory Board members represented, based on the Wagner data, that Celexa was safe and effective for pediatric use even though, unbeknownst to them, the FDA had specifically rejected

Forest's attempt to gain approval for such a claim because of the negative Lundbeck data.

57. During details to physicians, Forest's sales representatives made false or misleading representations by distributing off-label publications on the pediatric use of Celexa and Lexapro that did not include the negative Lundbeck data. Forest sales managers, also unaware of the Lundbeck data, directed the dissemination of these publications.

58. Forest had a Professional Affairs Department that responded to health care provider inquiries. Under the company's own written policy, the Professional Affairs Department was:

> *required to provide balanced information* to help the health care practitioner (HCP) make the best decision on behalf of the patient. For this reason, *there is an ethical prohibition in "cherry picking" studies that are favorable to Forest products*. The Food and Drug Administration Division of Drug Marketing, Advertising, and Communications (DDMAC) monitors drug information departments to insure information provided to HCPs is balanced, and that it is not selective.

(Emphasis added.) Forest's failure to disclose the negative Lundbeck data to its Professional Affairs Department caused it to disseminate misleading information to physicians on the pediatric use of Celexa and Lexapro. When physicians sought information from Forest's Professional Affairs Department in the years following the un-blinding of the Wagner and Lundbeck studies, the Professional Affairs Department responded with letters that cited only positive data. The letters cited just one double-blind placebo-controlled trial on the use of Celexa to treat pediatric depression, the Wagner Study. The letters never mentioned that there was another, negative, double-blind placebo-controlled trial, the Lundbeck study.

59. Several senior Forest executives – including Lawrence Olanoff (then Forest's

Chief Scientific Officer and now its President), Ivan Gergel (Vice President of Clinical Development and Medical Affairs), and Amy Rubin (Director of Regulatory Affairs) – reviewed the letters before the Professional Affairs Department disseminated them. All of these senior Forest executives knew about the negative Lundbeck data.

60. Forest paid a medical writing firm to ghost-write an academic article on the Wagner study, and Forest arranged to have the article published in the June 2004 issue of *The American Journal of Psychiatry*, with Dr. Wagner listed as the lead author. The article did not mention that the only other double-blind, placebo-controlled trial on pediatric use of Celexa had shown no efficacy and had an incidence of suicide attempts and suicidal ideation among those taking Celexa that was almost three times higher than in the group taking the placebo.

61. On June 21, 2004, *The New York Times* published a news story titled "Medicine's Data Gap – Journals in a Quandry; How to Report on Drug Trials." The story featured *The American Journal of Psychiatry* article on the Wagner study, revealing the negative results of the Lundbeck study and noting that the Wagner article failed to mention them.

62. Three days after the story ran, Forest issued a press release acknowledging the existence of the Lundbeck study and its finding that Celexa "did not show efficacy versus placebo." That same day, Forest also disclosed the results of an earlier double-blind placebo-controlled study of Lexapro in children and adolescents. That study also failed to show efficacy in comparison to placebo.

63. By failing to disclose the Lundbeck study results, which raised serious questions about the efficacy and safety of Celexa, while simultaneously promoting the Wagner study,

Forest told prescribing physicians a half-truth and thereby prevented them and the public from having all potentially available information when making decisions about how to treat a serious medical condition in pediatric patients.

64. Forest's conduct regarding the Lundbeck study results was consistent with the way it handled prior negative study data on Celexa. Just a few months before the pediatric Lundbeck study was unblinded, senior executives from Forest and Lundbeck discussed whether publicly to disclose the negative results from a study of Celexa in a primary care population. The study included three groups: patients taking Lexapro, patients taking Celexa, and patients taking placebo. Although Lexapro showed efficacy versus the placebo in the study, Celexa did not. Minutes of a December 2000 meeting of senior Forest and Lundbeck executives show that Forest wanted to publicize only the Lexapro versus placebo results, while Lundbeck wanted the results from the entire study to be publicly disclosed. As Lundbeck executives noted a month earlier, "Forest made clear their concern over disclosing any data that could put Celexa in an unfavorable light." In May 2001, Lundbeck executives observed that "Forest are at the moment unwilling to release data where citalopram does not sufficiently surpass placebo." Forest ultimately prevailed over Lundbeck and, as it did later with Lundbeck's negative pediatric data, kept the negative Celexa versus placebo results confidential.

C. Forest's Fraudulent Course Of Conduct To Promote Celexa And Lexapro For Off-Label, Pediatric Use

65. To obtain FDA approval for a drug, a drug must be demonstrated to be safe and effective for each of its proposed uses. The approved uses for a drug are limited to those uses identified in the FDA-approved product label. *See* 21 U.S.C. § 355(a), (b). "Off-label" use

refers to the promotion of an approved drug for any purpose, or in any manner, other than what is described in the drug's FDA-approved labeling.

66. From 1998 through at least 2005, Forest engaged in a widespread campaign to promote Celexa and Lexapro for pediatric use, even though neither drug was approved for pediatric use and the science was, at best, inconclusive about the safety and efficacy of these drugs for pediatric use. Forest used its sales representatives to detail or target pediatric specialists; paid pediatric specialists to give promotional speeches to other physicians on pediatric use; selectively distributed publications on pediatric uses to pediatric specialists; misrepresented the safety and effectiveness of the drugs; and made extensive payments and gifts to induce physicians to prescribe Celexa and Lexapro for pediatric uses.

67. Forest knew that its off-label promotion for pediatric use was unlawful. Shortly before the FDA ordered the black box warning in September 2004, a Forest executive testified before Congress: "I want to emphasize that, because the FDA has not approved pediatric labeling for our products, Forest has always been scrupulous about not promoting the pediatric use of our antidepressant drugs, Celexa and Lexapro. That is the law, and we follow it." In fact, Forest had been illegally promoting the pediatric use of Celexa and Lexapro throughout the preceding six years.

68. Forest assigned its sales representatives to specific geographic regions across the United States. Within each region, sales representatives encouraged specific doctors to increase their prescriptions of Celexa and Lexapro. A specific component of this marketing scheme included the promotion of Celexa and Lexapro for pediatric indications.

69. From 1998 through the end of 2004, the lists of physicians whom Forest directed its sales representatives to target, also known as "call panels," included thousands of child psychiatrists, pediatricians, and other physicians who specialized in treating children. Forest had more than 500,000 promotional sales calls or "details" with these pediatric specialists. The sales representatives documented these details through "call notes." Forest recorded thousands of call notes evidencing pediatric promotion. Examples of such notes include the following:

- "discussed cx [Celexa] use in children . . . and results of dr. karen wagner study regarding cx use for children and adolescents."
- "went over peds use, 0 drug interactions, less ae, less compliance issues for children, he is sold on that. closed on keeping cx first choice."
- "went over Celexa children, the invitation to the winery."
- "[doctor] trying in children and asked if [Lexapro] could be dissolved in water for children. Told him to crush and put in apple sauce. Liked idea!"
- "discuss lx [Lexapro] brief and what he [is] using dosing w children . . . reinforce safety for children."
- "Let him know some child psychs are using LX for children."
- "Discussed children and adolescents with ADH[D] and how Lexapro fits in to treat the anxiety and depression and OCD."
- "dinner program [with child psychiatrist as speaker] at amato's with yale child study center."
- "focus on Lexapro efficacy at just 10mg..great choice for child/adolescents."
- "mainly sees children but always felt comfortable with CX & children - got his commitment to give [Lexapro] a fair clinical trial."

- "went over lxp use on children and efficacy."

Call notes such as these represent only some of the instances when sales representatives memorialized their illegal off-label promotion of Celexa and Lexapro. The call notes exemplify the tip of what was a much more pervasive and widespread off-label campaign.

70. Forest's headquarters office in New York maintained a list of "approved" promotional speakers that included numerous pediatric specialists. Forest sales representatives and managers identified speakers from these lists to organize promotional lunches and dinners on Celexa and Lexapro. As late as 2005, approximately 14% of Forest's 2,680 approved speakers were pediatric specialists. Many of the Forest promotional programs for Celexa and Lexapro explicitly focused on off-label pediatric use: the programs had titles such as "Adolescent Depression," "Adolescent Treatment of Depression," "Updates in Depression," "Depression," "Treatment of Child/Adolescent Mood Disorders," "New Treatment Options in Depressive Disorders in Adolescents," "New Age Depression Treatment," "Use of Antidepressants in Adolescents," "Benefits of SSRIs in Child Psychology," "Treating Depression and Related Illnesses in Children," "Adolescents, and Adults," "Celexa in CHP/Ped Practice," "Treating Difficult Younger Patients," "Treatment of Depression," "Assessment and Treatments of Suicidal Adolescents," and "Treating Pediatric Depression." Forest management approved each of these programs.

71. From 1999 through 2006, one pediatric specialist, Dr. Jeffrey Bostic, Medical Director of the Massachusetts Child Psychiatry Access Project at Massachusetts General Hospital, gave more than 350 Forest-sponsored talks and presentations, many of which addressed

pediatric use of Celexa and Lexapro. Dr. Bostic's programs, which took place in at least 28 states, had topics such as "Uses of Celexa in Children" and "Celexa Use in Children and Adolescents." Forest also paid Dr. Bostic to meet other physicians in their offices in order to ease their concerns about prescribing Celexa or Lexapro off-label for pediatric use.

72. Dr. Bostic became Forest's star spokesman in the promotion of Celexa and Lexapro for pediatric use. As one sales representative wrote, "DR. BOSTIC is the man when it comes to child Psych!" Between 2000 and 2006, Forest paid Bostic over $750,000 in honoraria for his presentations on Celexa and Lexapro.

D. Forest's Illegal Inducements To Physicians To Prescribe Celexa And Lexapro

73. Forest augmented its off-label promotion efforts through extensive payments and gifts to physicians to induce them to prescribe Celexa and Lexapro. Forest's marketing department directed some of the kickbacks, such as honoraria for participation in advisory boards and in a large marketing study on Lexapro. Forest's sales representatives, often acting with the knowledge and encouragement of their managers, arranged for other kickbacks, such as restaurant gift certificates for physicians, lavish entertainment of physicians and their spouses, and grants to individual physicians.

1. Advisory Boards

74. Between 2000 and 2005, Forest hosted over 900 local or regional "advisory boards" on Celexa and Lexapro, with over 19,000 advisory board attendees that Forest called "consultants." Forest paid each "consultant" an honorarium of $500.

75. Ostensibly, Forest paid physicians to attend these advisory boards to get their

feedback on the marketing of Celexa and Lexapro. In reality, as repeatedly reported in internal company documents, Forest intended that the advisory boards induce the attendees to prescribe more Celexa and Lexapro.

76. In a May 2000 proposal for a series of 44 Celexa advisory boards, a Forest contractor, Intramed, wrote that the advisory boards, each with 20 physicians attendees, would "give Forest an opportunity to influence more physicians." Forest's marketing department approved this proposal. Later that year, Steve Closter, the Forest marketing executive who organized the advisory boards, wrote that the Celexa advisory boards begun in June 2000 had been successful and, as a result, "will become an even larger part of the promotional mix in the future." For years thereafter, Forest's marketing department included the cost of advisory boards in its annual promotional budgets for Celexa and Lexapro.

77. With the early success of the advisory board programs, the Forest sales force enthusiastically used them to drive up sales. As one Forest District Manager told his Regional Director in a November 2000 planning document, he intended to conduct a local advisory board to "target[] the highest prescribers" in several of his territories because "[t]here is no doubt that a program of this magnitude will increase Celexa market share." In approximately January 2002, a marketing strategy slide deck given to Forest's chief executive, Howard Solomon, quoted a Regional Director stating that, "[w]ell planned Advisory Board meetings will be key to our efforts of reaching hesitant physicians."

78. In June 2002, Forest's two Vice Presidents of Sales sent a memorandum to all sales managers observing that, notwithstanding new promotional guidelines for the industry,

advisory boards remained among "the wealth of activities and programs that we can conduct that will impact physicians." Similarly, in August 2002, a Forest Regional Director sent an e-mail to his District Managers stating that, "[w]ith the new guidelines in place, Ad Boards have become even a more valuable resource, thus each one needs to be a home run! With your attention and focus, we can make [*sic*] maximize this opportunity!"

79. In the fall of 2002, to coincide with the launch of Lexapro, Forest conducted a series of 200 advisory boards reaching over 4,000 potential new Lexapro prescribers.

80. Forest monitored its return on investment, or "ROI," from the advisory boards. To conduct its ROI analyses, Forest measured the increase in prescriptions written by physicians that attended the local advisory boards, and then compared the value of those prescriptions to the cost – primarily the honoraria payments – of putting on the programs. A November 2000 ROI analysis of a single advisory board program reached the following conclusion:

> Post program the Ad Board group [24 attendees] wrote an average of 19.6% Celexa as measured by a 5-week 1st Rx average. This is an increase of 3.7% in share. At first glance, the share increase might not appear substantial. However, considering the volume of SSRIs written by these physicians, 3.7% translates into almost 2000 new prescriptions on a yearly basis.

81. In May 2001, an internal ROI analysis of all of the Celexa advisory boards in 2000 found that "participants in the program prescribed nearly 14 additional prescriptions of Celexa vs. the control group over a seven-month period."

82. Three months later, in August 2001, the author of the ROI analysis reiterated to the Celexa marketing team that, "[o]ur goal is to increase the ROI on these advisory boards." That same month, a Forest Regional Director reported to the company's Vice President of Sales

that three local advisory boards had "generated close to $30K" from just a subset of the attendees and that "the scripts will continue, and continue to generate additional $$$ and ROI."

83. After 2003, Forest stopped conducting ROI analyses of advisory boards because of concerns about memorializing illegal intent, but the company continued to use the same types of advisory board programs as a means of inducing doctors to prescribe Celexa and Lexapro. As a Forest Area Business Director noted in a September 2003 memorandum to his Regional Directors, "[w]e are not able to do as many Ad Boards as we have in the past, so it [is] critical that we get the best targets to the programs." Similarly, in March 2004, a Texas-based Forest District Manager reported to her Regional Director and fellow District Managers that she had met with her sales team about "the types of doctors" they wanted to recruit for an upcoming advisory board and that they had come "up with 40 doctors that are either high Celexa writers or can be converted/persuaded to write Lexapro." In August 2004, a Massachusetts District Manager wrote to his colleagues and sales team that, for an upcoming Lexapro advisory board, "we are looking for the best ROI."

2. The EXCEED Study

84. In 1998, Forest successfully used a so-called "seeding study" – a clinical study intended to induce participating physicians to prescribe the drug under study – as part of the promotional strategy for the launch of Celexa. With the launch of Lexapro in 2002, Forest sought to replicate the success of the Celexa seeding study. Forest called the Lexapro seeding study EXCEED (EXamining Clinical Experience with Escitalopram in Depression).

85. In the planning stages for EXCEED, a senior Forest marketing executive wrote

that the purpose of the study was to ensure a "fast uptake" for Lexapro. The overall Lexapro marketing plan, which was reviewed by the company's most senior executives, stated:

> Another component of the rapid uptake of Lexapro will be to encourage trial. The experience trial for Lexapro (EXCEED) will follow approval and will be larger in scope than the Celexa experience trial (EASE). More prescribers will have the ability to trial Lexapro on several patients to gain experience. Trial leads to adoption and continued usage of a product if a prescriber has successful results.

At the conclusion of EXCEED, Forest's marketing department planned to calculate the study's "ROI," *i.e.*, the number of prescriptions generated as compared against the cost of funding the study.

86. To the extent the EXCEED trial had a scientific purpose, it was secondary to the purpose of inducing participating physicians to prescribe Lexapro. Forest conceived the study as a promotional tool and then sought out company scientists "to discuss possible endpoints/outcomes to look at for our early usage trial." Forest hired Covance, a contract research organization, to conduct the study, but, according to Covance's own study implementation plan, Covance, too, understood that "the primary goal of this trial is to provide experience to physicians." Similarly, Forest openly referred to the EXCEED trial as a "seeding" study in their internal communications.

87. Forest aimed the EXCEED study at 2,000 physicians. Under the study protocol, each participating physician could enroll up to five patients in the study, which would last eight weeks and involve three patient visits. After the first visit, the physician would fill out a one-page form with the patient's age, race, gender, and basic medical history, and Forest would pay the physician $50. After each of the next two visits, the physician would fill out an additional

page requiring the physician to write the date of the visit and to check one of seven boxes describing the change, if any, in the patient's condition. After the physician completed this additional page and two other pages showing the patient's Lexapro dosing information and any adverse events or concomitant medications, Forest would pay the physician an additional $100. Forest ultimately allowed physicians to enroll up to ten patients in the study, so that physicians could make up to $1,500 for starting patients on Lexapro, plus an extra $100 if the physician dialed in to a pre-study teleconference.

88. By the time the EXCEED study was completed, Forest had made study participation payments to 1,053 physicians, who in turn put 5,703 patients on Lexapro during the course of the study.

3. Preceptorships

89. Between 1999 and 2003, Forest paid millions of dollars to physicians who participated in so-called "preceptorships." Each physician who participated in a preceptorship received a "grant" of as much as $1,000 per preceptorship.

90. Ostensibly, preceptorships were a training opportunity where Forest sales representatives would spend a half-day or full day with a physician and learn about how Celexa and Lexapro were used in practice. In reality, Forest sales representatives used the preceptorships to induce physicians to prescribe Celexa and Lexapro.

91. Forest was fully aware of how sales representatives actually used preceptorships. Company policy mandated that sales representatives fill out "Return on Investment (R.O.I.)" forms to obtain approval to pay a doctor for a preceptorship. Each ROI form provided for a

statement of the amount of the payment to the physician and a projection of how many incremental prescriptions the preceptorship would cause, along with an estimate of the dollar value of those prescriptions to Forest. Thus, the preceptorship ROI forms enabled Forest to evaluate whether a payment to a participating physician was intended to induce an increase in prescriptions sufficient to justify the cost to Forest. Senior Forest sales managers and headquarters staff reviewed and approved the completed preceptorship ROI forms.

92. The preceptorship ROI forms also provided for sales representatives to write narrative justifications for the preceptorship payments, included the following:

- "Dr. ___ is the managing partner of the '____ Psychiatric Group' and is very influential among his colleagues in the ___ Hospital network. He currently averages @ 12 per week on 1st RX. His #s are trending up even till this day + we need to keep a good thing going as long as we are still getting this kind of growth from Dr. ___."

- "Dr. ___ is the largest prescriber of SSRI's in a 3 state area. . . . We are currently her first line SSRI. We must, however, continue to support her monetarily or this will not continue to be the case. . . . We have to keep the pressure on to continue to receive the growth we are getting with Dr. ___."

- "Dr. ___ is my largest prescribing Celexa physician. He is a high maintenance target and doing round tables and preceptorships will help me to keep his business and to continue to grow his business."

- "2 different preceptorhsips. Doc is 3rd ranked phys. in SSRI potential + bus had dropped. Needed his full attention."

- "Dr. ___ is my fourth largest SSRI writer. . . . A preceptorship will provide opportunity for rapport and for future detail time and sales."

- "# 1 physician in Territory. . . . Dr. ___ is on the verge of writing a lot of Celexa. Will present new studies during preceptorship."

- "This full day preceptorship will give me the opportunity to sell Celexa as a first-line choice in doctor ___'s practice."

- "To influence doctor to Rx Celexa."

Forest approved all of these preceptorship payment justifications.

4. Lavish Entertainment And Gifts

93. During the period from 1998 through at least 2005, each Forest sales representative typically had a quarterly marketing budget of thousands of dollars to spend on physicians. As a Forest Regional Director put it in an April 2006 memo to his sales team, "we have a ton of promotional money." Forest sales managers put pressure on their sales representatives to spend their entire marketing budgets.

94. Prior to 2003, Forest sales representatives commonly spent their marketing money on fishing, golf, and spa outings for physicians, and on buying tickets to sporting events and the theater for physicians. Both prior to and after 2003, Forest sales representatives also attempted to induce physicians to prescribe Celexa and Lexapro by spending their marketing budgets on restaurant gift certificates, subsidies for physician office parties, and lavish entertainment that could be disguised on an expense report as meals accompanying a supposed exchange of scientific information. Examples of these various types of kickbacks include the following:

- In 1998, a District Manager (whom Forest later named to be its nationwide Director of Compliance) arranged for sales representatives in his district to give St. Louis Cardinals tickets to physicians on the condition, he said, that the tickets be "leveraged and sold as a reward for prescriptions" and that "A Solid Return on Investment can be demonstrated."

- In September 2002, a sales representative gave a high-prescribing

child psychiatrist a $1,000 gift certificate to Alain Ducasse, a New York restaurant that at the time was one of the most expensive in the United States.

- In June 2001, two Forest sales representatives took a physician and his three sons on a deep sea fishing trip off Cape Cod, Massachusetts.

- In June 2002, a sales representative arranged a salmon fishing charter cruise for four physicians in his territory.

- In February 2002, a sales representative purchased $400 in Broadway theater tickets for a physician and his wife.

- In February 2002, a Division Manager purchased $2,276 in Boston Red Sox tickets for his sales representatives to use, he said, "throughout the next six months with all of our key targets."

- From 2001 to 2005, Forest sales representatives in North Carolina repeatedly arranged social dinners for a psychiatrist who ran multiple offices and reportedly was the highest prescriber of Celexa and Lexapro in the state.

- From 2001 to 2005, Forest sales representatives in Louisiana repeatedly paid for a physician and his family to eat at some of the most expensive restaurants in that state; one of those sales representatives reported that the physician had promised he would "always rxlex [*i.e.*, prescribe Lexapro] #1 aslong [*sic*] as we have fun and take care of him."

95. All of this spending was intended to induce physicians to prescribe Celexa or Lexapro.

VII. FALSE CLAIMS

96. As a result of Forest's fraudulent course of conduct, Forest caused the submission of false or fraudulent claims for Celexa and Lexapro to federal health care programs. These claims were not reimbursable because they were not covered for off-label pediatric use and/or

were ineligible for payment as a result of illegal kickbacks.

97. The chart set forth below identifies examples of false or fraudulent claims caused by Forest's off-label promotion. The chart includes: (a) the prescribing physician; (b) the number of promotional sales calls by Forest to each physician; (c) the number of pediatric Medicaid claims resulting from that physician; and (d) the amount paid for those pediatric claims by Medicaid.

CELEXA			
Physician	No. of Calls by Forest	Pediatric Claims	Medicaid Payment
Dr. A.	58	1927	$110,865
Dr. B.	70	977	$70,311
Dr. C.	133	871	$85,980
Dr. D.	58	777	$42,568
Dr. E.	33	586	$44,280
Dr. F.	50	589	$39,807
LEXAPRO			
Physician	No. of Calls by Forest	Pediatric Claims	Medicaid Payment
Dr. G.	257	1769	$197,052
Dr. H.	118	7790	$428,627
Dr. I.	76	4565	$251,378
Dr. J.	192	3219	$229,469
Dr. K.	296	2441	$252,879

98. The chart set forth below provides examples of false or fraudulent claims caused by Forest's illegal kickbacks to a physician, Dr. L. The chart identifies: (a) the year; (b) the type

of meeting or event Dr. L attended; (c) the amount paid to Dr. L; (d) the number of claims resulting from Dr. L; and (e) the amount paid for those claims by Medicaid.

Year	Type of Meeting or Event	Amount Paid	Claims	Medicaid Payment
2000	Advisory Boards	$500	197	$12,867
2001	Advisory Boards/Speaker Programs	$1,250	221	$14,646
2002	Advisory Boards/Speaker Programs/ Sponsorships	$2,500	367	$25,570
2003	Advisory Boards/Speaker Programs/Sponsorships	$10,250	302	$21,175
2004	Sponsorships	$500	272	$20,402

FIRST CAUSE OF ACTION
(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1))

99. The United States repeats and realleges the preceding paragraphs as if fully set forth herein.

100. Forest knowingly caused to be presented false or fraudulent claims for payment or approval to the United States for Celexa and Lexapro prescriptions that were not covered for off-label pediatric use, and/or were ineligible for payment as a result of illegal kickbacks.

101. By virtue of the false or fraudulent claims that Forest caused to be made, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than $5,000 and up to $10,000 for each violation occurring before September 29, 1999, and not less than $5,500 and up to $11,000 for each violation occurring on or after September 29, 1999.

SECOND CAUSE OF ACTION
(Unjust Enrichment)

102. The United States repeats and realleges the preceding paragraphs as if fully set forth herein.

103. The United States claims the recovery of all monies by which Forest has been unjustly enriched.

104. As a consequence of the acts set forth above, Forest was unjustly enriched at the expense of the United States in an amount to be determined which, under the circumstances, in equity and good conscience, should be returned to the United States.

PRAYER FOR RELIEF

WHEREFORE, the United States demands and prays that judgment be entered in its favor against Forest as follows:

1. On the First Count under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief as may be just and proper.

2. On the Second Count for unjust enrichment, for the damages sustained and/or amounts by which Forest was unjustly enriched or by which Forest retained illegally obtained monies, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

DEMAND FOR JURY TRIAL

The United States demands a jury trial in this case.

Respectfully submitted,

MICHAEL F. HERTZ
ACTING ASSISTANT ATTORNEY GENERAL

MICHAEL J. SULLIVAN
UNITED STATES ATTORNEY

Dated: February 13, 2009 By: _____

GREGG D. SHAPIRO
Assistant United States Attorney
United States Attorney's Office
John Joseph Moakley U.S. Courthouse
1 Courthouse Way, Suite 9200
Boston, MA 02210
(617) 748-3366

JOYCE R. BRANDA
JAMIE ANN YAVELBERG
SANJAY M. BHAMBHANI
EVA U. GUNASEKERA
Attorneys, Civil Division
United States Department of Justice
P.O. Box 261, Ben Franklin Station
Washington, D.C. 20044
(202) 305-0546

FILED UNDER SEAL

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, ex rel. JAMES WETTA,	)	
Plaintiff,	)	C.A. No. 04-3479
v.	)	Filed Under Seal
ASTRAZENECA CORPORATION,	)	
Defendant.	)	

UNITED STATES' NOTICE OF INTERVENTION FOR PURPOSES OF SETTLEMENT

The United States of America, by and through its undersigned attorneys, provides this written notice to the Court that it is intervening in the above-captioned action pursuant to 31 U.S.C. §3730(b) for the purposes of settlement and dismissal.

The United States, relator James Wetta and defendant AstraZeneca have reached an amicable resolution of these matters. A copy of the Settlement Agreement is attached as Exhibit A. The parties agree that, upon receipt of the Settlement Amount as defined in the Settlement Agreement, the United States and relator will file a Stipulation of Dismissal in accordance with

the terms of the Settlement Agreement.

Respectfully submitted,

MICHAEL L. LEVY
United States Attorney

VIRGINIA A. GIBSON
First Assistant United States Attorney

COLIN M. CHERICO
Assistant United States Attorney

EXHIBIT A

SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the United States Department of Justice and the United States Attorney's Office for the Eastern District of Pennsylvania, the Office of Inspector General of the United States Department of Health and Human Services ("OIG-HHS"), the TRICARE Management Activity ("TMA"), and the United States Office of Personnel Management ("OPM") (collectively the "United States"); James Wetta ("Wetta"); Stephan Kruszewski, M.D. ("Kruszewski"); and Astra Zeneca LP and AstraZeneca Pharmaceuticals LP (collectively, "AstraZeneca"), through their authorized representatives. Collectively, all of the above will be referred to as "the Parties."

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. AstraZeneca LP and AstraZeneca Pharmaceuticals LP are Delaware limited partnerships with their principal places of business in Wilmington, Delaware. At all relevant times herein, AstraZeneca distributed, marketed and sold pharmaceutical products in the United States, including a drug sold under the trade name of Seroquel.

B. On July 24, 2004, Wetta filed a qui tam action in the United States District Court for the Eastern District of Pennsylvania captioned United States of America ex rel. James Wetta v. AstraZeneca Corporation, Civil Action No. 04-3479 (hereinafter "Civil Action I").

C. On September 8, 2006, Kruszewski filed a qui tam action in the United States District Court for the Eastern District of Pennsylvania captioned United States of America ex rel. Stephan Kruszewski v. AstraZeneca Pharmaceuticals LP, Civil Action No. 06-4004

(hereinafter "Civil Action II"). Civil Action I and Civil Action II hereinafter may be referred to collectively as the "Civil Actions."

D. AstraZeneca has entered or will be entering into separate settlement agreements, described in Paragraph 1(b), below (hereinafter referred to as the "Medicaid State Settlement Agreements") with certain states and the District of Columbia in settlement of the Covered Conduct. States with which AstraZeneca executes a Medicaid State Settlement Agreement in the form to which AstraZeneca and the National Association of Medicaid Fraud Control Units ("NAMFCU") Negotiating Team have agreed, or in a form otherwise agreed to by AstraZeneca and an individual State, shall be defined as "Medicaid Participating States."

E. The United States and the Medicaid Participating States allege that AstraZeneca caused claims for payment for Seroquel to be submitted to the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (the Medicaid Program).

F. The United States further alleges that AstraZeneca caused claims for payment for Seroquel to be submitted to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. § 1395-1395hhh; the TRICARE program, 10 U.S.C. §§ 1071-1109; the Federal Employees Health Benefits Program ("FEHBP"), 5 U.S.C. §§ 8901-8914; the Federal Employees Compensation Act Program, 5 U.S.C. § 8101 et seq; and caused purchases of Seroquel by the Department of Veterans' Affairs ("DVA"), Department of Defense, and the Bureau of Prisons ("BOP") (collectively, the "other Federal Health Care Programs").

G. The United States contends that it has certain civil claims, as specified in Paragraph 2, below, against AstraZeneca for engaging in the following conduct during the period January 1, 2001 through December 31, 2006 (hereinafter referred to as the "Covered Conduct"):

(1) AstraZeneca promoted the sale and use of Seroquel to psychiatrists, other physicians (including primary care physicians) and other health care professionals in pediatric and primary care physician offices, in long-term care facilities and hospitals and in prisons for certain uses that were not approved by the Food and Drug Administration as safe and effective for those uses (including aggression, Alzheimer's disease, anger management, anxiety, attention deficit hyperactivity disorder, bipolar maintenance, dementia, depression, mood disorder, post-traumatic stress disorder, and sleeplessness) ("unapproved uses"). AstraZeneca also promoted the unapproved uses by engaging in the following conduct: AstraZeneca improperly and unduly influenced the content of and speakers in company-sponsored Continuing Medical Education programs; engaged doctors to give promotional speaker programs it controlled on unapproved uses for Seroquel; engaged doctors to conduct studies on unapproved uses of Seroquel; recruited doctors to serve as authors of articles largely prepared by medical literature companies about studies they did not conduct on unapproved uses of Seroquel; and, used those studies and articles as the basis for promotional messages about unapproved uses of Seroquel. These unapproved uses were not medically accepted indications for which the United States and the state Medicaid programs provided coverage for Seroquel.

(2) AstraZeneca offered and paid illegal remuneration to doctors: (a) it recruited to conduct studies for unapproved uses, (b) it recruited to serve as authors of articles written by AstraZeneca and its agents about these unapproved uses of Seroquel, (c) to travel to resort locations to "advise" AstraZeneca about marketing messages for unapproved uses of Seroquel, and (d) it recruited to give promotional lectures to other health care professionals about unapproved and unaccepted uses of Seroquel. The United States contends that these payments were intended to induce the doctors to promote and/or prescribe Seroquel for unapproved uses in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320-7b(b).

As a result of the foregoing conduct, the United States contends that AstraZeneca knowingly caused false or fraudulent claims for Seroquel to be submitted to, or caused purchases by, Medicaid, Medicare and the other Federal Health Care Programs.

H. The United States also contends that it has certain administrative claims against AstraZeneca, as set forth in Paragraphs 4 through 6, below, for engaging in the Covered Conduct.

I. This Agreement is made in compromise of disputed claims. This Agreement is neither an admission of facts or liability by AstraZeneca nor a concession by the United States that its claims are not well founded. AstraZeneca expressly denies the allegations of the United States, the Medicaid Participating States, Wetta and Kruszewski as set forth herein and in Civil Action I and Civil Action II and denies that it has engaged in any wrongful conduct. Neither this Agreement, its execution, nor the performance of any obligation under it, including any payment, nor the fact of settlement, are intended to be, or shall be understood as, an admission of liability or wrongdoing, or other expression reflecting on the merits of the dispute by AstraZeneca.

J. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, the Parties reach a full and final settlement pursuant to the Terms and Conditions below.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the Parties agree as follows:

1. AstraZeneca agrees to pay to the United States and the Medicaid Participating States, collectively, the sum of Five Hundred and Twenty Million Dollars ($520,000,000), plus

accrued interest at the rate of 3% per annum from December 1, 2009, and continuing until and including the date of payment (the "Settlement Amount"). Payments shall be made as follows:

(a) AstraZeneca shall pay to the United States the sum of $301,907,007, plus accrued interest as set forth above ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions from the United States no later than ten (10) business days after the Effective Date of this Agreement.

(b) AstraZeneca shall pay to the Medicaid Participating States the sum of $218,092,993, plus accrued interest as set forth above ("Medicaid State Settlement Amount") pursuant to written instructions from the NAMFCU Negotiating Team and under the terms and conditions of the Medicaid State Settlement Agreements that AstraZeneca will enter into with the Medicaid Participating States.

(c) Contingent upon the United States receiving the Federal Settlement Amount from AstraZeneca, the United States agrees to pay, as soon as feasible after receipt, to Wetta $45,286,051, plus a pro rata share of the actual accrued interest paid to the United States by AstraZeneca, as set forth in Paragraph 1(a), above, ("Relator's Share") as relator's share of the proceeds pursuant to 31 U.S.C. § 3730(d). No other relator payments of any sort shall be made by the United States to Wetta and/or Kruszewski with respect to the matters covered by this Agreement.

(d) Wetta and Kruszewski have entered into a separate agreement under which Kruszewski will receive a portion of the Relator's Share.

2. Subject to the exceptions in Paragraph 7, below, in consideration of the obligations of AstraZeneca in this Agreement, conditioned upon AstraZeneca's full payment of

the Settlement Amount, the United States (on behalf of itself, its officers, agents, agencies, and departments) agrees to release AstraZeneca, together with AstraZeneca's predecessors, current and former parents, affiliates, direct and indirect subsidiaries, brother or sister entities, divisions, transferees, successors and assigns, and all of their current or former directors, officers and employees (hereinafter, collectively "AstraZeneca Releasees") from any civil or administrative monetary claim the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; any statutory provision for which the Civil Division of the Department of Justice has actual and present authority to assert and compromise pursuant to 28 C.F.R. Part O, Subpart I, Section 0.45(D); or the common law theories of payment by mistake, unjust enrichment, fraud, disgorgement of illegal profits, and, if applicable, breach of contract.

3. In consideration of the obligations of AstraZeneca in this Agreement, conditioned upon AstraZeneca's full payment of the Settlement Amount, Wetta and Kruszewski, for themselves and for their heirs, successors, attorneys, agents, and assigns, fully and finally release the AstraZeneca Releasees from any claim the United States has, may have or could have asserted related to the Covered Conduct, and from all liability, claims, demands, actions or causes of action whatsoever existing as of the Effective Date of this Agreement, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or regulation or that they or their heirs, successors, attorneys, agents and assigns otherwise would have standing to bring, including any liability arising from the filing of the Civil Actions, except for any claims they may have under 31 U.S.C. § 3730(d) and/or 31 U.S.C.

§ 3730(h).

4. In consideration of the obligations of AstraZeneca in this Agreement and the Corporate Integrity Agreement ("CIA"), entered into between OIG-HHS and AstraZeneca, conditioned upon AstraZeneca's full payment of the Settlement Amount, OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)), against AstraZeneca under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in Paragraph 7 below, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude AstraZeneca from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

5. In consideration of the obligations of AstraZeneca set forth in this Agreement, conditioned upon AstraZeneca's full payment of the Settlement Amount, TMA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the TRICARE Program, against AstraZeneca under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph 7, below, and as reserved in this Paragraph. TMA expressly reserves authority to exclude AstraZeneca under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii), based upon the Covered Conduct. Nothing in this Paragraph

precludes TMA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

6. In consideration of the obligations of AstraZeneca in this Agreement, conditioned upon AstraZeneca's full payment of the Settlement Amount, OPM agrees to release and refrain from instituting, directing, or maintaining any administrative action, against AstraZeneca under 5 U.S.C. § 8902a or 5 C.F.R. Part 919 or Part 970 for the Covered Conduct, except as reserved in Paragraph 7, below and except as required by 5 U.S.C. §8902a(b). Nothing in this Paragraph precludes OPM from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

7. Notwithstanding any term of this Agreement, the following claims of the United States are specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including AstraZeneca, Wetta and/or Kruszewski):

(a) Any civil, criminal, or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

(b) Any criminal liability;

(c) Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;

(d) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

(e) Any liability based upon such obligations as are created by this Agreement;

(f) Any liability for express or implied warranty claims or other claims for

defective or deficient products or services, including quality of goods and services;

(g) Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; and

(h) Any liability for failure to deliver goods or services due.

8. Wetta and Kruszewski and their heirs, successors, attorneys, agents, and assigns agree not to object to this Agreement and agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B) and, conditioned upon the United States' payment of the Relator's Share, as set forth in Paragraph 1(c), above, Wetta and Kruszewski, for themselves individually, and for their heirs, successors, agents, and assigns, fully and finally release, waive, and forever discharge the United States, and its officers, agents, and employees, from any claims arising from or relating to 31 U.S.C. § 3730; from any claims arising from the filing of Civil Action I and/or Civil Action II; and from any other claims for a share of the Settlement Amount or payment of any sort from the United States relating to the Settlement Agreement or the filing of Civil Action I and/or Civil Action II; and in full settlement of any claims Wetta and/or Kruszewski may have under this Agreement. This Agreement does not resolve or in any manner affect any claims the United States has or may have against Wetta and/or Kruszewki arising under Title 26, U.S. Code (Internal Revenue Code), or any claims arising under this Agreement.

9. AstraZeneca waives and shall not assert any defenses AstraZeneca may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth

Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

10. AstraZeneca fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that AstraZeneca has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

11. Conditioned upon Wetta and Kruszewski's compliance with their obligations under this Agreement, AstraZeneca fully and finally releases Wetta and Kruszewski from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that AstraZeneca has asserted, could have asserted, or may assert in the future against Wetta and/or Kruszewksi, related to the Covered Conduct and Wetta and/or Kruszewski's investigation and prosecution thereof, except to the extent related to claims Wetta or Kruszewski may have under 31 U.S.C. § 3730(d) and/or 31 U.S.C. § 3730(h).

12. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or intermediary or any other state or Federal payer, related to the Covered Conduct; and AstraZeneca agrees not to resubmit to any Medicare carrier or intermediary or any other state or Federal payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such

denials of claims.

13. AstraZeneca agrees to the following:

(a) Unallowable Costs Defined: that all costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh and 1396-1396v; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of AstraZeneca, its present or former officers, directors, employees, shareholders and agents in connection with the following shall be "Unallowable Costs" on government contracts and under the Medicare Program, Medicaid Program, TRICARE Program, and FEHBP:

(i) the matters covered by this Agreement;

(ii) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;

(iii) AstraZeneca's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);

(iv) the negotiation and performance of this Agreement;

(v) the payment AstraZeneca makes to the United States pursuant to this Agreement and any payments that AstraZeneca may make to Wetta and/or Kruszewski, including costs and attorneys fees; and

(vi) the negotiation of, and obligations undertaken pursuant to the CIA to:

(a) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and

(b) prepare and submit reports to the OIG-HHS.

However, nothing in this paragraph 13(a)(vi) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to AstraZeneca. (All costs described or set forth in this Paragraph 13(a) are hereafter "Unallowable Costs.")

(b) Future Treatment of Unallowable Costs: If applicable, these Unallowable Costs shall be separately determined and accounted for by AstraZeneca, and AstraZeneca shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by AstraZeneca or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

(c) Treatment of Unallowable Costs Previously Submitted for Payment: If applicable, AstraZeneca further agrees that within 90 days of the Effective Date of this Agreement, it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by AstraZeneca or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the

effect of the inclusion of the unallowable costs. AstraZeneca agrees that the United States, at a minimum, shall be entitled to recoup from AstraZeneca any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by AstraZeneca or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on AstraZeneca or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

(d) Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine AstraZeneca's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

14. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for above or in Paragraph 15 (waiver for beneficiaries paragraph), below.

15. AstraZeneca agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

16. AstraZeneca warrants that it has reviewed its financial situation and that it

currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall remain solvent following payment to the United States of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to AstraZeneca, within the meaning of 11 U.S.C. § 547(c)(1); and (b) have concluded that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which AstraZeneca was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

17. Upon receipt of the payments described in Paragraph 1, above, the United States and Wetta shall promptly sign and file in Civil Action I a Notice of Intervention and Joint Stipulation of Dismissal with prejudice as to all federal counts in Civil Action I pursuant to the terms and conditions of the Agreement. Upon receipt of the payments described in Paragraph 1, above, Kruszewski shall promptly sign and file in Civil Action II a Notice of Dismissal with prejudice as to all federal counts in Civil Action II pursuant to the terms and conditions of the Agreement.

18. Except as expressly provided to the contrary in this Agreement, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

19. AstraZeneca represents that this Agreement is freely and voluntarily entered into

without any degree of duress or compulsion whatsoever.

20. Wetta and Kruszewski represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

21. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement is the United States District Court for the Eastern District of Pennsylvania, except that disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions in the CIA.

22. For purposes of construction, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

23. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

24. The individuals signing this Agreement on behalf of AstraZeneca represent and warrant that they are authorized by AstraZeneca to execute this Agreement. The individual(s) signing this Agreement on behalf of Wetta and Kruszewski represent and warrant that they are authorized by Wetta and Kruszewski to execute this Agreement. The United States signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

25. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

26. This Agreement is binding on AstraZeneca's successors, transferees, heirs, and

assigns.

27. This Agreement is binding on Wetta and Kruszewski's successors, transferees, heirs, and assigns.

28. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

29. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 4-27-10 BY: _____
MICHAEL L. LEVY
United States Attorney
United States Attorney's Office
Eastern District of Pennsylvania

DATED: 4-27-10 BY: _____
VIRGINIA A. GIBSON
First Assistant
United States Attorney's Office
Eastern District of Pennsylvania

DATED: 4-27-10 BY: _____
MARGARET L. HUTCHINSON
Chief, Civil Division
United States Attorney's Office
Eastern District of Pennsylvania

DATED: 4-27-10 BY: _____
COLIN CHERICO
Assistant U.S. Attorney
United States Attorney's Office
Eastern District of Pennsylvania

DATED: _____ BY: _____
PATRICIA L. HANOWER
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

THE UNITED STATES OF AMERICA

DATED:_____ BY: _____
MICHAEL L. LEVY
United States Attorney
United States Attorney's Office
Eastern District of Pennsylvania

DATED:_____ BY: _____
VIRGINIA A. GIBSON
First Assistant
United States Attorney's Office
Eastern District of Pennsylvania

DATED:_____ BY: _____
MARGARET L. HUTCHINSON
Chief, Civil Division
United States Attorney's Office
Eastern District of Pennsylvania

DATED:_____ BY: _____
COLIN CHERICO
Assistant U.S. Attorney
United States Attorney's Office
Eastern District of Pennsylvania

DATED: 4/27/10 BY: _____
PATRICIA L. HANOWER
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 4/27/10 BY: _____
GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: _____ BY: _____
LAUREL C. GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

DATED: _____ BY: _____
SHIRLEY R. PATTERSON
Acting Deputy Associate Director Insurance Operations
Center for Retirement & Insurance Services
United States Office of Personnel Management

DATED: _____ BY: _____
DAVID COPE
Debarring Official
Office of the Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

DATED:_____ BY: _____
GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: April 23, 2010 BY: Rhonda L. Bershok, Acting Deputy General Counsel
For: LAUREL C. GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

DATED:_____ BY: _____
SHIRLEY R. PATTERSON
Acting Deputy Associate Director Insurance Operations
Center for Retirement & Insurance Services
United States Office of Personnel Management

DATED:_____ BY: _____
DAVID COPE
Debarring Official
Office of the Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

DATED:_____ BY: _____
GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED:_____ BY: _____
LAUREL C. GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

DATED: 4/26/10 BY: Shirley R Patterson
SHIRLEY R. PATTERSON
Acting Deputy Associate Director Insurance Operations
Center for Retirement & Insurance Services
United States Office of Personnel Management

DATED: 4/26/2010 BY: _____
DAVID COPE
Debarring Official
Office of the Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

ASTRAZENECA

DATED: 4/27/10 BY: _____

Glenn M. Engelmann
Vice President and General Counsel
AstraZeneca LP
AstraZeneca Pharmaceuticals LP

DATED: 4/27/10 BY: _____

JOHN C. DODDS, ESQ.
Morgan, Lewis and Bockius, LLP

RELATOR JAMES WETTA

DATED:_____ BY: _____
JAMES WETTA

DATED:_____ BY: _____
STEPHEN A. SHELLER, ESQ.

(Counsel to Relator James Wetta)

RELATOR JAMES WETTA

DATED: 4/23/10

BY: James Wetta by Michael Mustokoff
JAMES WETTA

DATED: 4/23/10

BY: Stephen A. Sheller
STEPHEN A. SHELLER, ESQ.

(Counsel to Relator James Wetta)

BY: Michael Mustokoff
MICHAEL MUSTOKOFF
MARK LIPOWICZ
TERESA CAVENAGH
DUANE MORRIS, LLP

BY: Gary M. Farmer by Michael Mustokoff
GARY M. FARMER JR.
FARMER JAFFE WEISSING EDWARDS FISTOS and LEHRMAN

[redacted]

RELATOR STEPHAN KRUSZEWSKI

DATED: 4/23/2010 BY: _____
STEFAN KRUSZEWSKI

DATED: _____ BY: _____
WILLIAM LEONARD, ESQUIRE
(Counsel to Stephan Kruszewski)

RELATOR STEPHAN KRUSZEWSKI

DATED:_____ BY: _____
STEFAN KRUSZEWSKI

DATED: 4/23/10 BY: _____
WILLIAM LEONARD, ESQUIRE
(Counsel to Stephan Kruszewski)