CHAPTER 302—RELOCATION ALLOWANCES

PART 302–6—ALLOWANCE FOR TEMPORARY QUARTERS SUBSISTENCE EXPENSES

■ 28. The authority citation for 41 CFR part 302–6 is revised to read as follows:

Authority: 5 U.S.C. 5738; 20 U.S.C. 905(a); E.O. 11609, as amended, 3 CFR, 1971–1973 Comp., p. 586.

§ 302–6.2 [Amended]

■ 29. Amend § 302–6.2 by removing the word "local".

■ 30. Revise § 302–6.18 to read as follows:

§ 302–6.18 May I be reimbursed for transportation expenses incurred while I am occupying temporary quarters?

Transportation expenses incurred in the vicinity of the temporary quarters are not TQSE, and therefore, there is no authority to pay such expenses under TQSE.

PART 302–9—ALLOWANCES FOR TRANSPORTATION AND EMERGENCY STORAGE OF A PRIVATELY OWNED VEHICLE

■ 31. The authority citation for 41 CFR part 302–9 is revised to read as follows:

Authority: 5 U.S.C. 5738; 20 U.S.C. 905(a); E.O. 11609, as amended, 3 CFR, 1971–1973 Comp., p. 586.

§ 302–9.10 [Amended]

■ 32. Amend § 302–9.10, by removing the word "local" wherever it appears.

[FR Doc. 2010–10235 Filed 5–4–10; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 424 and 431

[CMS–6010–IFC]

RIN 0938–AQ01

Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period implements several provisions set forth in the Patient Protection and Affordable Care Act (Affordable Care Act). It implements the provision which requires all providers of medical or other items or services and suppliers that qualify for a National Provider Identifier (NPI) to include their NPI on all applications to enroll in the Medicare and Medicaid programs and on all claims for payment submitted under the Medicare and Medicaid programs. This interim final rule with comment period also requires physicians and eligible professionals to order and refer covered items and services for Medicare beneficiaries to be enrolled in Medicare. In addition, it adds requirements for providers, physicians, and other suppliers participating in the Medicare program to provide documentation on referrals to programs at high risk of waste and abuse, to include durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), home health services, and other items or services specified by the Secretary.

DATES: *Effective date:* These regulations are effective on July 6, 2010. *Comment date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on July 6, 2010.

ADDRESSES: In commenting, please refer to file code CMS–6010–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed).

- *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions for submitting comments on the home page.
- *By regular mail.* You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6010–IFC, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

- *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6010–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.
- *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Patricia Peyton, (410) 786–1812 for Medicare issues. Rick Friedman, (410) 786–4451 for Medicaid issues.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday

through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

The Medicare program, title XVIII of the Social Security Act (the Act), is the primary payer of health care for 42 million enrolled beneficiaries. Under section 1802 of the Act, a beneficiary may obtain health services from an individual or an organization qualified to participate in the Medicare program. Qualifications to participate are specified in statute and in regulations (see, for example, sections 1814, 1815, 1819, 1833, 1834, 1842, 1861, 1866, and 1891 of the Act); and 42 CFR chapter IV, subchapter E, which concerns standards and certification requirements).

Providers and suppliers furnishing services must comply with the Medicare requirements stipulated in the Act and in our regulations. These requirements are meant to ensure compliance with applicable statutes, as well as to promote the furnishing of high quality care. As Medicare program expenditures have grown, we have increased our efforts to ensure that only qualified individuals and organizations are allowed to enroll or maintain their Medicare billing privileges.

Medicaid is a joint Federal and State health care program for eligible low-income individuals. States have considerable flexibility in how they administer their Medicaid programs within a broad Federal framework and programs vary from State to State.

The Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148) makes a number of changes to the Medicaid program, strengthening tools for quality and integrity, adding new benefits, and expanding coverage. To maintain program integrity and assure quality, it is consistent with these changes to assure that only qualified providers participate in the program and that these providers bill accurately for their services. Although our regulations provide States with considerable flexibility, the Federal framework includes some key requirements to ensure program integrity and quality care. For example, Medicaid providers must generally meet all State licensing and scope-of-practice requirements, and may be subject to additional Federal and State quality standards. Additionally, our regulations require timely filing of claims by providers.

Including the NPI on claims and enrollment applications is an important step in controlling fraud and abuse, ensuring a unique identifier so that States can assure that only qualified Medicaid providers have provider agreements and maintain their Medicaid billing privileges. This practice implements the requirement in section 1128J(e) of the Act, as added by section 6402(a) of the Affordable Care Act and will also help in implementing other important protections under the Affordable Care Act that ensure quality health care services for program beneficiaries.

A. Statutory Authority

The following is an overview of the sections that grant this authority.

- Sections 1102 and 1871 of the Act provide general authority for the Secretary of Health and Human Services (the Secretary) to prescribe regulations for the efficient administration of the Medicare program.
- Section 1128J(e) of the Act, added by section 6402(a) of the Affordable Care Act, requires that the Secretary require by regulation that all providers of medical or other items or services and suppliers under titles XVIII and XIX that are eligible for a national provider identifier (NPI) include the NPI on all applications to enroll in such programs and on all claims for payment under such programs.
- Sections 1814(a), 1815(a), and 1833(e) of the Act require the submission of information necessary to determine the amounts due a provider or other person.
- Section 1834(j)(1)(A) of the Act states that no payment may be made for items furnished by a supplier of medical equipment and supplies unless such supplier obtains (and renews at such intervals as the Secretary may require) a supplier number. In order to obtain a supplier number, a supplier must comply with certain supplier standards as identified by the Secretary.
- Section 1842(r) of the Act requires the Centers for Medicare and Medicaid Services (CMS) to establish a system for furnishing a unique identifier for each physician who furnishes services for which payment may be made.
- Section 1862(e)(1) of the Act states that no payment may be made when an item or service was at the medical direction of an individual or entity that is excluded in accordance with sections 1128, 1128A, 1156, or 1842(j)(2) of the Act.
- Section 4313 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) amended sections 1124(a)(1) and 1124A of the Act to require disclosure of both the Employer Identification Number (EIN) and Social Security Number (SSN) of each provider or supplier, each person with ownership or control interest in the provider or supplier, any subcontractor in which the provider or supplier directly or indirectly has a 5 percent or more ownership interest, and any managing employees including Directors and Board Members of corporations and non-profit organizations and charities. The "Report to Congress on Steps Taken to Assure Confidentiality of Social Security Account Numbers as Required by the Balanced Budget Act" was signed by the Secretary and sent to the Congress on January 26, 1999. This report outlines the provisions of a mandatory collection of SSNs and EINs effective on or after April 26, 1999.
- Section 4312(a) of the Balanced Budget Act of 1997 amended section 1834(a)(16) of the Act by requiring certain Medicare suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) to furnish CMS with a surety bond. Section 4312(b) requires that a surety bond be in an amount of not less than $50,000.
- Section 31001(i)(1) of the Debt Collection Improvement Act of 1996 (DCIA) (Pub. L. 104–134) amended section 7701 of 31 U.S.C. by adding paragraph (c) to require that any person or entity doing business with the Federal Government must provide their Taxpayer Identification Number (TIN).
- Section 936(j)(1)(A) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended the Act to require the Secretary to establish a process for the enrollment of providers of services and suppliers.

We are authorized to collect information on the Medicare enrollment application (that is, the CMS–855, (Office of Management and Budget (OMB) approval number 0938–0685)) to ensure that correct payments are made to providers and suppliers under the Medicare program as established by title XVIII of the Act.

- Section 1902(a)(27) of the Act provides general authority for the Secretary to require provider agreements under the Medicaid State Plans with every person or institution providing services under the State Plan. Under these agreements, the Secretary may require information regarding any payments claimed by such person or institution for providing services under the State plan.

B. Historical Enrollment Initiatives

Historically, Medicare has permitted the enrollment of providers and suppliers whose qualifications for meeting all of our enrollment standards were sometimes questionable. This has raised concern that providers and

suppliers in our program may be underqualified or even fraudulent and has led us to increase our efforts to establish more stringent controls on provider and supplier entry into the Medicare program. The following is a summary of the regulations that we have published over the past 10 years to ensure that only qualified providers and suppliers are participating in the Medicare program.

In the October 11, 2000 **Federal Register**, we published the Additional Supplier Standards final rule with comment period where we established additional standards with which a DMEPOS supplier must comply in order to receive and maintain Medicare billing privileges. This final rule with comment period outlined the supplier requirements to ensure that suppliers of DMEPOS are qualified to furnish DMEPOS and to help safeguard the Medicare program and its beneficiaries from fraudulent or abusive billing practices.

In the April 21, 2006, **Federal Register**, we published the Requirements for Providers and Suppliers to Establish and Maintain Medicare Enrollment final rule that implemented section 1866(j)(1)(A) of the Act. In this final rule, we required that all providers and suppliers (other than those who have elected to "opt-out" of the Medicare program) complete an enrollment application and submit specific information to CMS in order to obtain Medicare billing privileges. This final rule also required that all providers and suppliers must periodically update and certify the accuracy of their enrollment information to receive and maintain billing privileges in the Medicare program. These regulatory provisions include requirements to protect beneficiaries and the Medicare Trust Fund by preventing unqualified, fraudulent, or excluded providers and suppliers from providing items or services to Medicare beneficiaries or from billing the Medicare program or its beneficiaries.

In the December 1, 2006, **Federal Register** (71 FR 69624), we published a final rule titled, "Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; and Ambulance Inflation Factor Update for CY 2007." In part, this final rule with comment established performance standards for independent diagnostic testing facilities.

In the April 10, 2007, **Federal Register** (72 FR 17992), we published a final rule titled, "Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)." This final rule implemented section 302 of the MMA requiring that DMEPOS suppliers meet certain quality standards and established DME competitive bidding.

In the November 27, 2007 **Federal Register** (72 FR 66222), we published a final rule titled, "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Amendment of the E–Prescribing Exemption for Computer Generated Facsimile Transmissions; Final Rule." In this final rule, we clarified our interpretation of several of the existing independent diagnostic testing facility (IDTF) performance standards found at § 410.33(b) and § 410.33(g), proposed a new IDTF performance standard at § 410.33(g)(15), and a new proposed IDTF provision at § 410.33(i).

In the June 27, 2008, **Federal Register** (73 FR 36448), we published a final rule titled, "Appeals of CMS or CMS Contractor Determinations When a Provider or Supplier Fails to Meet the Requirements for Medicare Billing Privileges." This final rule implemented section 936 of the MMA and extended appeal rights to all providers and suppliers, including DMEPOS suppliers, whose enrollment applications for Medicare billing privileges are denied or revoked by CMS or a Medicare contractor (that is, carrier, fiscal intermediary, National Supplier Clearinghouse Medicare Administrative Contractor (MAC), or Part A/Part B MAC). This final rule also allowed providers and suppliers to seek judicial review after they have exhausted the administrative appeals process. In addition, this final rule also implemented provider enrollment provisions that apply to all provider and supplier types.

In the November 19, 2008, **Federal Register** (73 FR 69726), we published a final rule with comment titled, "Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E–Prescribing Exemption for Computer Generated Facsimile Transmissions; and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)." In part, this final rule with comment period established a number of provider enrollment provisions affecting physicians, non-physician practitioners, and other providers and suppliers, such as the re-enrollment bar of 1 to 3 years on revoked providers and suppliers, as well as the limitation on retroactive billing by providers and suppliers.

In the January 2, 2009, **Federal Register** (74 FR 166), we published a final rule titled, "Medicare Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); Final Rule." Consistent with section 4312(a) of the BBA, this final rule implemented section 1834(a)(16) of the Act by requiring certain Medicare suppliers of DMEPOS to furnish CMS with a surety bond of no less than $50,000.

Historically, the States in operating the Medicaid program have permitted the enrollment of providers and suppliers who meet the State requirements for Medicaid enrollment. Due to the increased risk of fraud and abuse in public health care programs of all types, the NPI requirement will strengthen cross-program integrity efforts.

II. Provisions of the Interim Final Rule With Comment Period

A. Inclusion of the National Provider Identifier (NPI) on all Medicare and Medicaid Enrollment Applications and Claims

1. Background

Section 1128J(e) of the Act builds on the past Congressional mandate to require the adoption of a unique identifier for health care providers and codifies the NPI requirements that Medicare is already requiring for its fee-for-service (FFS) providers and suppliers.

"Health care provider" is defined in the Health Insurance Portability and Accountability Act (HIPAA) definitions found at 45 CFR 160.103. With the exception of organ procurement organizations and Part B CAP drug vendors, the term "health care provider" includes all of the providers and suppliers who are eligible to enroll in the Medicare program and most who are eligible to enroll in the Medicaid program. In this discussion, we use the term "health care provider" when referring to HIPAA and HIPAA regulations, and we use "providers and suppliers" when referring to those health care providers who are eligible to enroll in the Medicare program.

In the January 23, 2004, NPI final rule (69 FR 3434), we adopted the NPI as the standard unique health identifier for health care providers. This fulfilled the

requirement of section 1173(b) of the Act, which was added by HIPAA. The final rule stated that HIPAA does not prohibit health plans from requiring their enrolled health care providers to obtain NPIs. Accordingly, the Medicare program required enrolling fee-for-service (FFS) providers and suppliers (and their subparts, in accordance with the NPI Final Rule) to report their NPIs on their Medicare enrollment applications beginning in May 2006. When FFS providers and suppliers who had enrolled prior to May 2006 submitted enrollment applications to update their enrollment information, they were required to report their NPIs on those enrollment applications. These requirements ensured that the Medicare provider and supplier enrollment records included the NPIs and, in effect, already implemented one of the provisions of section 1128J(e) of the Act.

In accordance with the NPI final rule and the subsequent guidance from the Secretary, beginning May 23, 2008, Medicare required its enrolled FFS providers and suppliers to use NPIs in their electronic claims to identify not only themselves as the billing providers, but any other providers or suppliers who, according to the Implementation Guides for the adopted standard claims transactions, were also required to be identified in those claims. These other health care providers include rendering providers, supervising providers, and ordering and referring providers. The regulations that adopted the HIPAA standard transactions are found at (65 FR 50312, 68 FR 8381, and 74 FR 3296). In addition, at that same time, Medicare required its enrolled FFS providers and suppliers to make this same use of NPIs in their paper claims.

The Provider Enrollment, Chain, and Ownership System (PECOS), implemented in 2003, is the national repository of enrolled Medicare FFS providers and suppliers (except DMEPOS suppliers, who will be added to PECOS later in 2010). PECOS contains the information furnished by providers and suppliers in their Medicare FFS enrollment applications and additional information added as required to keep the information current and to protect the integrity of the Medicare program (for example, fact and date of death, Office of Inspector General exclusions). In 2007, PECOS began sending the NPIs in the daily provider and supplier enrollment data extract going to the Part A and Part B FFS claims systems. In 2009, Medicare added the NPIs to the enrollment records of the DMEPOS suppliers, which are currently housed in the DMEPOS supplier enrollment repository at the National Supplier Clearinghouse MAC. After the DMEPOS supplier enrollment records are added to PECOS, PECOS will send a daily DMEPOS supplier enrollment data extract, which will include the NPIs, to the DMEPOS FFS claims system. Medicare FFS claims systems link the NPIs that are reported in claims with the appropriate enrollment records in order to properly price and pay the claims.

In summary, Medicare has been requiring its providers and suppliers to report their NPIs on their Medicare enrollment applications; its enrolled providers and suppliers to report their NPIs, and the NPIs of other providers and suppliers (as required and as explained previously) in their electronic and paper Medicare claims; and suppliers who order or refer covered items or services for Medicare beneficiaries to have NPIs so that they can be identified, as required, in the claims for the covered items and services that they have ordered and referred. Similarly, consistent with NPI final rule and subsequent guidance from the Secretary, beginning May 23, 2008, Medicaid providers have also been required to report their NPIs on their Medicaid claims. This IFC now requires their NPIs be submitted for Medicaid provider agreements.

2. Provisions of the Affordable Care Act

Section 6402(a) of the Affordable Care Act added a new section 1128J of the Act, entitled "Medicare and Medicaid Program Integrity Provisions." Section 1128J(e), as added by section 6402(a) of the Affordable Care Act, requires the Secretary to promulgate a regulation that requires, not later than January 1, 2011, all providers of medical or other items or services and suppliers under the programs under titles XVIII and XIX that qualify for a NPI to include their NPI on all applications to enroll in such programs and on all claims for payment submitted under such programs. In Medicaid, there is no Federally required process for provider enrollment except that all Medicaid providers are required to enter into a provider agreement with the State as a condition of participating in the program under section 1902(a)(27) of the Act. Therefore, in the Medicaid context we are including the submission of an NPI to the State agency as a requirement under the provider agreement. The NPI requirements in this IFC are thus applicable to the reporting of NPIs—(1) Pursuant to Medicaid provider agreements; (2) on Medicare provider and supplier enrollment applications; and (3) on Medicare and Medicaid claims.

3. Requirements Established by This IFC

For the Medicare program, we are establishing, at § 424.506(b), requirements that a provider or supplier who is eligible for an NPI must report the NPI on the Medicare enrollment application; and, if the provider or supplier enrolled in Medicare prior to obtaining an NPI and the NPI is not in the provider's or supplier's enrollment record, the provider or supplier must report the NPI to Medicare in an enrollment application so that the NPI will be added to the provider's or supplier's enrollment record in PECOS. We are also establishing, at § 424.506(b)(1), a requirement that a provider or supplier who is enrolled in fee-for-service (FFS) Medicare report its NPI, as well as the NPI of any other provider or supplier who is required to be identified in those claims, on any electronic or paper claims that the provider or supplier submits to Medicare. We are also establishing, at § 424.506(b)(2), that a claim submitted by a Medicare beneficiary contain the legal name and, if the beneficiary knows the NPI, the NPI of any provider or supplier who is required to be identified in that claim.

If a Medicare beneficiary does not know the NPI of a provider or supplier who is required to be identified in the claim that he or she is submitting, the beneficiary may submit the claim without the NPI(s) as long as the claim contains the legal name(s) of the health care provider(s). If a beneficiary so desires, he or she can obtain a provider's or a supplier's NPI by requesting it directly from the provider or supplier or from a member of his or her office staff, or by looking it up in the NPI Registry at *https://nppes.cms.hhs.gov/NPPES/NPIRegistryHome.do.*

Furthermore, we are establishing, at § 424.506(c)(3), that a Medicare claim from a provider or a supplier will be rejected if it does not contain the required NPI(s).

For the Medicaid program, we are establishing, at § 431.107(b)(5), a requirement that the agreement between a State agency and each provider furnishing services under the State plan include a requirement that any Medicaid provider eligible for an NPI furnish its NPI to the State agency under that agreement and on all Medicaid claims.

B. Ordering and Referring Covered Items and Services for Medicare Beneficiaries

1. Background

Section 1833(q) of the Act requires that claims for items or services for

which payment may be made under Part B and for which there was a referral by a referring physician shall include the name and the unique identification number of the referring physician. Physicians are doctors of medicine and osteopathy, optometry, podiatry, dental medicine, dental surgery, and chiropractic. Referring physicians are those who order covered items or services for Medicare beneficiaries from Medicare providers and suppliers as well as those who refer Medicare beneficiaries to Medicare providers and suppliers for covered services. We consider those who "refer" to also be authorized to "order." In this IFC, we refer to physicians who both order and refer as "ordering and referring suppliers" and the act of ordering items or services for Medicare beneficiaries or referring Medicare beneficiaries to other providers or suppliers for services as "ordering and referring."

The Implementation Guides for the adopted HIPAA standard transactions do not use the word "supplier" in their descriptions of the health care providers who must be identified in those transactions. For example, and as stated earlier in this preamble, the Implementation Guides use the terms "billing provider, ordering provider, referring provider" and others. Because this section of this IFC relates only to the Medicare program, and because the statute and regulations use the term "supplier" (not "provider") when referring to physicians and non-physician practitioners, we are using the term "ordering and referring suppliers" in this IFC. This term corresponds to "ordering provider" and "referring provider" described in the Implementation Guides.

The Medicare providers and suppliers who furnish the covered ordered or referred items and services send claims to Medicare for reimbursement for those covered items and services.

With the establishment and implementation of surrogate Unique Physician Identification Numbers (UPINs) in 1992, suppliers could be identified, but not uniquely identified, in claims as ordering and referring suppliers. These suppliers included physicians, physician assistants, clinical nurse specialists, nurse practitioners, clinical psychologists, certified nurse midwives, and clinical social workers.

Sections 6405(a) and (c) of the Affordable Care Act indicate that orders and referrals for DMEPOS and for other categories of items and services may be made by a physician or an "eligible professional under section 1848(k)(3)(B)." Section 1848(k)(3)(B) of the Act discusses covered professional services for which payment may be made under, or is based on, the fee schedule, and which are furnished by: (1) A physician; (2) a practitioner described in section 1842(b)(18)(C) of Act; (3) a physical or occupational therapist or a qualified speech-language pathologist; and (4) a qualified audiologist. Section 1842(b)(18)(C) of the Act discusses billing and payment for Medicare services furnished by physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives, clinical social workers, clinical psychologists, and registered dietitians or nutrition professionals. Neither section 1848(k)(3)(B) of the Act nor section 1842(b)(18)(C) of the Act discuss the issue of ordering or referring covered items or services for Medicare beneficiaries. Although section 6405(a) of the Affordable Care Act indicates that DMEPOS may be ordered by enrolled physicians or enrolled eligible professionals under section 1848(k)(3)(B) of the Act, our policy has not been to permit all of the eligible professionals listed in that section or in section 1842(b)(18)(C) of the Act to order and refer. Section 6405(c) of the Affordable Care Act gives the Secretary the discretion to determine the professions that can order and refer for all covered items and services under title XVIII that are not mentioned in sections 6405(a) and (b) of the Affordable Care Act (DMEPOS and home health, respectively). In addition, the claims processing edits that we established in 2009 require that the ordering and referring suppliers for DMEPOS and for laboratory, imaging, and specialist services be those physicians and professionals who were eligible for UPINs: Physicians, physician assistants, clinical nurse specialists, nurse practitioners, clinical psychologists, certified nurse midwives, and clinical social workers. In this IFC, the term eligible professional means any of the professionals listed in section 1848(k)(3)(B) of the Act. In this preamble, we distinguish physicians from eligible professionals (even though physicians are included in section 1848(k)(3)(B) as eligible professionals) because sections 6405(a) and (b) of the Affordable Care Act reference physicians separately from eligible professionals. Section 6405(c) of the Affordable Care Act gives the Secretary the discretion to determine the health professions that can order and refer items and services other than DMEPOS and home health.

In the past, prior to the Medicare implementation of the NPI on May 23, 2008, physicians and eligible professionals were identified in claims as ordering or referring suppliers by their UPINs. Physicians and eligible professionals applied for and were assigned UPINs as part of the process of enrolling in the Medicare program; therefore, physicians and eligible professionals were expected to be identified in claims as ordering or referring suppliers by their UPINs.

Surrogate UPINs were established to be used in claims to temporarily identify certain ordering and referring suppliers who had not yet completed the Medicare enrollment process and, therefore, had not yet been assigned UPINs. Surrogate UPINs were used to collectively identify the following: (1) Physicians who were serving in the military or with the Department of Veterans Affairs or the Public Health Service (including the Indian Health Service); (2) interns, residents, and fellows; and (3) retired physicians. There was also a surrogate UPIN (OTH000) that could be used for any other supplier who ordered or referred who could not be identified by any of the other surrogate UPINs.

Over time, providers and suppliers began using surrogate UPINs in their claims to identify ordering and referring suppliers who had been assigned their own UPINs, as well as individuals who had never been assigned UPINs. In addition, they also used UPINs that had been assigned to physicians other than the physicians who they were identifying in their claims as the ordering or referring suppliers. We believe that many providers and suppliers became aware that the use of any UPIN would get their claims processed and paid. They learned, over time, that Medicare claims edits on the ordering and referring suppliers were based on the format of the UPIN, and all UPINs had the same format. The claims process did not verify the UPINs of ordering or referring suppliers. These practices negated the intent of the UPIN, which was to uniquely identify the ordering or referring supplier.

Analysis of Medicare claims data prior to 2008 (UPINs were not permitted to be used in Medicare claims after May 23, 2008) revealed that these practices were widespread and, as a result, we had reason to believe that many physicians and eligible professionals were unaware of the requirement that their assigned UPINs were intended to uniquely identify them as ordering or referring suppliers and, more importantly, that they needed to apply for UPINs. As a result, Medicare may have paid claims for covered ordered and referred items and services that may

have been ordered or referred by professionals who were not of a profession eligible to order and refer; by physicians or eligible professionals who were not enrolled in the Medicare program; or by physicians or eligible professionals who were not in an approved Medicare enrollment status (for example, they were sanctioned, their licenses were suspended or revoked, their billing privileges were terminated, or they were deceased).

With the Medicare implementation of the NPI in May 2008, Medicare discontinued the assignment of UPINs and no longer allowed UPINs to be used in Medicare claims. Medicare required providers and suppliers who were sending claims to Medicare for covered ordered and referred items and services to use the NPI, rather than the UPIN, to identify the ordering and referring suppliers in their claims. Because the NPI Final Rule did not discuss the concept of "surrogate NPIs" nor did it contain a provision for the establishment of "surrogate NPIs," surrogate NPIs do not and cannot exist. Because physicians and non-physician practitioners are eligible for NPIs, only the NPI may be used in Medicare claims to identify ordering and referring suppliers.

We believe that the new requirements discussed below will address concerns expressed by the Department of Health and Human Services' (DHHS) Office of Inspector General (OIG) report titled, "Durable Medical Equipment Ordered with Surrogate Physician Identification Numbers, OEI–03–01–00270, September 2002," which found that the use of surrogate UPINs on Medicare claims poses a vulnerability to the Medicare program. The HHS OIG found a substantial number of documentation problems in the supporting evidence submitted by suppliers for claims processed with surrogate UPINs. The DHHS OIG estimated that, in 1999, Medicare paid $61 million for services ordered with a surrogate UPIN that had missing or incomplete supporting documentation. Finally, the DHHS OIG stated that the findings in its report also revealed misuse of surrogate UPINs on Medicare claims. The HHS OIG found that surrogate UPINs were incorrectly used for many services since the ordering physician had already been issued a permanent UPIN. The HHS OIG believed this to be a significant problem given that the use of a surrogate UPIN on medical equipment claims allows them to be processed automatically whether the equipment has been ordered by a physician or not. The HHS OIG stated that the inappropriate use of surrogate UPINs by suppliers goes unchecked, the Medicare program becomes vulnerable to fraudulent billings and inappropriate payments.

To ensure the unique identification of ordering and referring suppliers and that they were qualified to order and refer, Medicare implemented claims edits in 2009 that require the ordering and referring suppliers identified in Part B claims for items of DMEPOS and services of laboratories, imaging suppliers, and specialists be identified by their legal names and their NPIs and that they have enrollment records in PECOS. Claims edits are under development to ensure that claims for Part A and Part B home health services identify the physicians who ordered the home health services by their legal names and their NPIs and that those physicians have enrollment records in PECOS.

2. Provisions of the Affordable Care Act

Section 6405(a) amended section 1834(a)(11)(B) of the Act to specify, with respect to suppliers of durable medical equipment, that payment may be made under that subsection only if the written order for the item has been communicated to the DMEPOS supplier by a physician who is enrolled under section 1866(j) of the Act or an eligible professional under section 1848(k)(3)(B) who is enrolled under section 1866(j) before delivery of the item. Section 1128J(e) requires that he or she be identified by his or her NPI in claims for those services. Medicare requires the ordering supplier (the physician or the eligible professional) to be identified by legal name and NPI in the claim submitted by the supplier of DMEPOS.

Section 10604 of the Affordable Care Act, amended section 6405(b) of the Affordable Care Act as follows: (1) Section 1814(a)(2) of the Act to specify, with respect to home health services under Part A, that payment may be made to providers of services if they are eligible and only if a physician enrolled under section 1866(j) of the Act certifies (and recertifies, as required) that the services are or were required in accordance with section 1814(a)(1)(C) of the Act; and (2) section 1835(a)(2) of the Act to specify, with respect to home health services under Part B, that payments may be made to providers of services if they are eligible and only if a physician enrolled under section 1866(j) of the Act certifies (and recertifies, as required) that the services are or were medically required in accordance with section 1835(a)(1)(B) of the Act. Section 1128J(e) requires that the physician be identified by his or her NPI in claims for those services. Medicare requires the ordering supplier (the physician) to be identified by legal name and NPI in the claim submitted by the provider of home health services.

In addition, section 6405(c) of the Affordable Care Act gives the Secretary the authority to extend the requirements made by subsections (a) and (b) to all other categories of items or services under title XVIII of the Social Security Act, including covered Part D drugs as defined in section 1860D–2(e) of the Act, that are ordered, prescribed, or referred by a physician enrolled under section 1866(j) of the Act or an eligible professional under section 1848(k)(3)(B) of the Act. Section 1128J(e) requires that he or she be identified by his or her NPI in claims for those services. Medicare requires the ordering or referring supplier (the physician or the eligible professional) to be identified by legal name and NPI in the claims submitted by the suppliers of laboratory, imaging, and specialist services. These amendments are effective on or after July 1, 2010.

3. Requirements of This IFC

To ensure that ordering suppliers (physicians and eligible professionals) are uniquely identified in Medicare claims for covered items of DMEPOS as required by section 6405(a) of the Affordable Care Act, and to ensure that those DMEPOS items are ordered by qualified physicians or eligible professionals, we are requiring at a new § 424.507(a), the following:

- In Part B claims for covered items of DMEPOS that require the identification of the ordering supplier, and with the exception noted below, the ordering supplier be a physician or an eligible professional with an approved enrollment record in PECOS (see the exception below), and be identified in the claim by his or her legal name and by his or her own NPI (that is, by the NPI that was assigned to him or her by the National Plan and Provider Enumeration System [NPPES] as an Entity type 1 [an individual]).

To ensure that ordering suppliers are uniquely identified in Medicare Part A claims for covered Part A or Part B home health services as required by section 6405(b), as amended by section 10604 of the Affordable Care Act, and to ensure that those home health services are ordered by qualified physicians, we are requiring at a new § 424.507, the following:

- In Part A claims for covered Part A and Part B home health items or services that require the identification of the ordering supplier, and with the exception noted below, the ordering supplier be a physician with an approved enrollment record in PECOS

(see the exception below), and be identified in the claim by his or her legal name and by his or her own NPI (that is, by the NPI that was assigned to him or her by the National Plan and Provider Enumeration System [NPPES] as an Entity type 1 [an individual]).

To ensure that ordering or referring suppliers are uniquely identified in Part B claims for covered services of laboratories, imaging suppliers, and specialists, under the discretion afforded the Secretary in section 6405(c), and to ensure that those items or services are ordered or referred by qualified physicians or eligible professionals, we are requiring at a new § 424.507(b), the following:

• In Part B claims for covered services of laboratories, imaging suppliers, and specialists that require the identification of the ordering or referring supplier, and with the exception noted below, the ordering or referring supplier be a physician or an eligible professional with an approved enrollment record in PECOS (see the exception below), and be identified in the claim by his or her legal name and by his or her own NPI (that is, by the NPI that was assigned to him or her by the National Plan and Provider Enumeration System (NPPES) as an Entity Type 1 (an individual).

We are requiring at a new § 424.507(c) that Medicare contractors will reject claims from providers and suppliers for the above-described covered ordered or referred items or services if the legal names and the NPIs are not reported in the claims or, with the exception noted below, if the ordering or referring supplier does not have an approved enrollment record in PECOS.

We are requiring at a new § 424.507(d) that Medicare contractors may deny a claim submitted by a Medicare beneficiary for the above-described ordered or referred covered items and services if the ordering or referring supplier is not identified by his or her legal name or, with the exception noted below, if the ordering or referring supplier does not have an approved enrollment record in PECOS.

Our continuing outreach efforts stress the need for those who order and refer to have approved enrollment records in PECOS.

While we are not including additional categories of ordered or referred covered items or services in this IFC (such as Part B drugs), we reserve the right to apply these requirements to additional categories through future rulemaking once the policies have been developed. We are considering proposing the requirements for covered prescribed Part B drugs within the next year.

A physician or eligible professional who orders or refers must be enrolled in the Medicare program by having an enrollment record in an approved status in PECOS, even if he or she is enrolled only for the purposes of ordering and referring. To ensure that orders and referrals for Medicare beneficiaries are written by qualified physicians and eligible professionals, it is necessary that their credentials be verified; such verification can occur only as part of the Medicare provider/supplier enrollment process. PECOS, as described earlier in this preamble, is the national Medicare FFS provider and supplier enrollment repository. All providers and suppliers who enrolled in Medicare within the past 6 years, as well as those who enrolled more than 6 years ago and who have submitted updates to their enrollment information within the past 6 years, have enrollment records in PECOS that contain verified credentials. Those who enrolled more than 6 years ago and who have not updated their enrollment information in the past 6 (or more) years will need to submit enrollment applications to Medicare to establish enrollment records in PECOS. They may do this by filling out the paper Medicare provider enrollment applications (using the appropriate form(s) from the CMS–855 series of forms) and mailing the completed application(s) to the appropriate Medicare enrollment contractor or by using Internet-based PECOS to submit their enrollment application to the Medicare enrollment contractor over the Internet. With the implementation in 2009 of the claims processing edits to ensure the NPI and the name reported in claims to identify the ordering or referring suppliers matched information in PECOS for physicians and professionals of a profession eligible to order and refer, many enrolled physicians and eligible professionals who do not have enrollment records in PECOS are submitting enrollment applications in order to establish those enrollment records. We expect that most, if not all, of them will have submitted enrollment applications before the end of 2010, including those who are enrolling solely to continue to order and refer. A physician or eligible professional who is deceased, retired, or excluded from the Medicare program, or who otherwise would not have an approved enrollment record in PECOS, would not be eligible to order or refer items or services for Medicare beneficiaries. Please note the following exception for physicians and eligible professionals who do not have an approved enrollment record in PECOS:

Under section 1802(b) of the Act and the implementing regulations at 42 CFR 405.400 *et seq.,* physicians and non-physician practitioners can opt out of the Medicare program and enter into private contracts with Medicare beneficiaries. By entering into these types of contracts, these suppliers do not bill the Medicare program for services that they furnish to Medicare beneficiaries. We require that physicians and eligible professionals who have properly filed an appropriate affidavit with a Medicare contractor in order to opt out of the Medicare program be required to be identified in claims by their names and their NPIs if they order or refer covered items or services for Medicare beneficiaries. We are creating an exception to the requirement that ordering and referring suppliers be required to have an approved enrollment record in PECOS for those physicians and non-physician practitioners who have validly opted out of the Medicare program. Therefore, physicians and non-physician practitioners who have validly opted out of Medicare are eligible to order and refer covered items and services for Medicare beneficiaries. If they have properly completed the appropriate affidavit in order to opt out of Medicare, they will have records in PECOS that contain their NPIs and that indicate that they have validly opted out of the Medicare program. In January 2009, there were approximately 10,000 physicians and eligible professionals who had opted out of the Medicare program. Compared to the more than 800,000 enrolled physicians and eligible professionals, there are relatively few physicians and eligible professionals who have opted out of Medicare.

Accordingly, the physicians or eligible professional that opted out must meet the following:

• A currently enrolled physician or eligible professional who does not have an enrollment record in PECOS is required to establish an enrollment record in PECOS so that he or she can order and refer covered items or services for Medicare beneficiaries. A physician or eligible professional who has validly opted out of the Medicare program will have a valid opt-out record in PECOS and is not required to submit an enrollment application.

• A physician or eligible professional who is employed by the Public Health Service, the Department of Defense, or the Department of Veterans Affairs is required to have an approved enrollment record in PECOS in order to order and refer covered items and services for Medicare beneficiaries, even though he or she would not be

submitting claims to Medicare for services furnished to Medicare beneficiaries. We require, therefore, that these physicians and eligible professionals enroll in Medicare solely to order and refer (and not to be paid for services furnished to Medicare beneficiaries).

• A dentist furnishes many services that are not covered by Medicare and, as a result, most dentists are not enrolled in Medicare. However, a dentist may order services for patients who are Medicare beneficiaries, such as sending oral specimens to laboratories for testing. Doctors of dental medicine or dental surgery are considered physicians and we require that they have approved enrollment records in PECOS if they order or refer covered items or services for patients who are Medicare beneficiaries.

• A pediatrician may treat Medicare beneficiaries (for example, those of any age who are enrolled in the Medicare end-stage renal disease (ESRD) program or those who are entitled to Medicare benefits under other Federal programs), although the volume of such patients is generally so low that most pediatricians are not enrolled in Medicare. We require that a pediatrician have an approved enrollment record in PECOS if he or she orders or refers covered items or services for patients who are Medicare beneficiaries.

• Residents and interns order and refer covered items and services for Medicare beneficiaries. Prior to the implementation of the NPI, residents and interns were identified in claims as the ordering or referring providers by surrogate UPINs. Interns are not issued medical licenses by States; therefore, they are not eligible to enroll in Medicare. Residents have medical licenses if they practice in States that issue medical licenses to residents; as a result, some residents are eligible to enroll in Medicare. Due to the variances in licensure and the necessity for interns and residents to be able to continue to order and refer covered items and services for Medicare beneficiaries, we require that the teaching physician—not the resident or intern—be identified in the claim as the ordering or referring provider whenever a resident or intern orders or refers.

These ordering and referring requirements, when implemented, will allow us to uniquely identify the ordering and referring supplier in claims (except when the teaching physician is identified as the ordering or referring supplier in situations where an intern or a resident ordered or referred) and assure, because of the requirement to have an approved enrollment or valid opt out record in PECOS, that the ordering and referring supplier is qualified to order and refer items and services for Medicare beneficiaries. This will enable us to edit claims for ordering and referring suppliers who do not have approved enrollment records in PECOS (that is, those who are excluded, deceased, or retired, and those whose Medicare billing privileges have been terminated through exclusion, revocation, or otherwise), and those who have voluntarily terminated their relationship with Medicare or who have validly opted out of Medicare.

Further, we are requiring that Part A claims for covered ordered Part A and Part B home health services must include the legal name and the NPI of the ordering supplier, who must be a physician. We are requiring that Part B claims for covered, ordered, and referred Part B items and services (excluding Part B drugs) must include the legal name and the NPI of the ordering or referring supplier. We place these same requirements (except for the NPI) on claims submitted by Medicare beneficiaries for these same ordered or referred items and services. Although suppliers are required to submit claims on behalf of beneficiaries under the mandatory claim submission policy at section 1848(g)(4)(A) of the Act, we recognize that beneficiaries may submit claims to Medicare for payment. In order to fully enforce the ordering and referring requirement established by section 6405 of the Affordable Care Act, we plan to deny a beneficiary claim for a service when the legal name of the ordering or referring supplier is not included on the claim.

We believe that these requirements will promote quality health care services for Medicare beneficiaries because orders and referrals would be written by qualified physicians and eligible professionals, as their credentials would have been verified as part of the Medicare provider/supplier enrollment process.

Additionally, we believe these requirements will eliminate the abusive practice of reporting identifiers in claims as being assigned to specific ordering or referring suppliers when, in fact, those identifiers had not been assigned to those specific ordering or referring suppliers. As a result, our requirements should eliminate these types of problematic claims and ensure the qualifications of the ordering and referring suppliers.

Our requirements will enable us to know the identity of the individual who ordered or referred and, if appropriate, we could establish edits to check for over-ordering specific items or services, over-referring specific services, and/or over-ordering or over-referring to specific providers of services and suppliers.

Furthermore, these requirements support our existing authority, at § 424.516(f), under which the ordering and referring suppliers, and those providers of services and suppliers who furnish covered items or services based on orders or referrals, are required to maintain documentation (to include the NPI) that supports the orders and referrals for 7 years in order to maintain an active enrollment status in the Medicare program.

Lastly, these requirements may lead to a reduction in inappropriate Medicare payments.

We are aware that, in some cases, Medicare beneficiaries may be patients of physicians or eligible professionals who do not have approved enrollment records in PECOS, or may be patients of professionals who are not of a profession that is eligible to order or refer, and that these physicians and professionals may be ordering and referring covered items and services for these Medicare beneficiaries at this time. We expect to conduct outreach activities to educate Medicare beneficiaries, as well as Medicare providers of services and suppliers who furnish covered items and services based on orders and referrals, so that we can eliminate situations where those providers of services and suppliers who would be furnishing covered ordered and referred items and services would not be paid for those covered items or services because their claims failed the edits.

Finally, we believe that the requirements will address the recommendations offered by the DHHS OIG report titled, "Medicare Payments in 2007 for Medical Equipment and Supply Claims with Invalid or Inactive Referring Physician Identifiers, OEI–04–08–00470, February 2009." Specifically, the OIG recommended that CMS:

(1) Determine why Medicare claims with identifiers associated with deceased referring physicians continue to be paid;

(2) Implement claims-processing system changes to ensure that NPIs for both referring physicians and suppliers be listed on medical equipment and supply claims are valid and active.

(3) Emphasize to suppliers the importance of using accurate NPIs for both referring physicians and suppliers when submitting Medicare claims; and

(4) Determine the earliest date to end the provision that allows suppliers to submit claims without referring

physician NPIs while maintaining beneficiary access to services.

With respect to recommendation (4), we began requiring Medicare claims to identify ordering and referring providers by NPIs beginning May 23, 2008. If the provider of services or the supplier submitting the claim for the covered ordered or referred items or services could not determine the NPI of the ordering or referring supplier, we permitted the provider of services or the supplier submitting the claim to use its own NPI in place of the NPI of the ordering or referring provider. These types of claims for DMEPOS items now fail the claims processing edits that were implemented in 2009. Medicare-enrolled physicians and professionals are required to have NPIs. The NPI Registry (available at *https://nppes.cms.hhs.gov/NPPES/NPIRegistryHome.do*) enables anyone with a computer with Internet access to look up a health care provider's NPI by name or NPI, and the NPPES downloadable file (downloadable from *http://nppesdata.cms.hhs.gov/CMS_NPI_files.html*) contains the NPIs of all health care providers who have active NPIs, as well as identifying information about the health care providers that is publicly disclosable under the Freedom of Information Act. (The National Plan and Provider Enumeration System Data Dissemination Notice, published in the May 30, 2007 **Federal Register**, further describes the NPI Registry and the NPPES downloadable file.) The existing claims processing edits described earlier in this preamble check to ensure that the NPI reported on a Part B claim for ordered or referred covered items or services (excluding Part B home health services and Part B drug claims) belongs to the ordering or referring supplier whose name is also reported in those claims, and not to the supplier who submitted the claim. As stated previously, the provisions of section 6405 of the Affordable Care Act are effective July 1, 2010.

C. Requirement for Physicians, Other Suppliers, and Providers to Maintain and Provide Access to Documentation on Referrals to Programs at High Risk of Waste and Abuse

1. Background

On November 19, 2008, we published a final rule with comment titled, "Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; Revisions to the Amendment of the E–Prescribing Exemption for Computer Generated Facsimile Transmissions; and the Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)" in the **Federal Register**. In this IFC, we established § 424.516(f) to require providers and suppliers to maintain ordering and referring documentation, including the NPI, received from a physician or eligible non-physician practitioner. We also established in § 424.516(f) that physicians and eligible professionals are required to maintain written ordering and referring documentation for 7 years from the date of service. Finally, we established in § 424.535(a)(10) that failure to comply with the documentation requirements specified in § 424.516(f) is a reason for revocation.

2. Provisions of the Affordable Care Act

Section 6406 of the Affordable Care Act amends section 1866(a)(1) of the Act and added a new subparagraph (W) which requires providers to agree to "maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by the provider under this title, as specified by the Secretary."

In addition, section 6406 of the Affordable Care Act amended section 1842(h) of the Act by adding a new paragraph which states, "The Secretary may revoke enrollment, for a period of not more than one year for each act, for a physician or supplier under section 1866(j) if such physician or supplier fails to maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by such physician or supplier under this title, as specified by the Secretary."

Section 6406(b)(3) of the Affordable Care Act amends section 1866(a)(1) of the Act to require that providers and suppliers maintain and, upon request, provide to the Secretary, access to written or electronic documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by the provider as specified by the Secretary. Section 6406(b)(3) does not limit the authority of the Office of Inspector General to fulfill the Inspector General's responsibilities in accordance with applicable Federal law.

3. Requirements of This IFC

In our requirements, in our revision of § 424.516(f), we are replacing the term "eligible non-physician practitioner" with "eligible professional." This change is consistent with our definition of "eligible professional" and correctly identifies the professionals who, in addition to physicians, are eligible to order and refer.

At this time, we are expanding § 424.516(f) to include requirements for documentation and access to documentation related to orders and referrals for covered home health, laboratory, imaging, and specialist services. Section 424.516(f) currently includes requirements for documentation and access to documentation for orders for DMEPOS. We reserve the right to, at a future date, publish proposed requirements for documentation and access to documentation for additional items and services that may be ordered or referred under title XVIII and that are programs of high risk of waste and abuse.

We are revising the existing § 424.516(f) to now read "Maintaining and providing access to documentation." A provider or a supplier who furnishes covered ordered DMEPOS or referred home health, laboratory, imaging, or specialist services is required to maintain documentation for 7 years from the date of service and, upon the request of CMS or a Medicare contractor, to provide access to that documentation. The documentation includes written and electronic documents (including the NPI of the physician who ordered the home health services and the NPI of the physician or the eligible professional who ordered or referred the DMEPOS, laboratory, imaging, or specialist services) relating to written orders and requests for payments for items of DMEPOS and home health, laboratory, imaging, and specialist services. A physician who ordered home health services and a physician and an eligible professional who ordered or referred items of DMEPOS or laboratory, imaging, and specialist services is required to maintain documentation for 7 years from the date of the order, certification, or referral and, upon request of CMS or a Medicare contractor, to provide access to that documentation. The documentation includes written and electronic documents (including the NPI of the physician who ordered the home health services and the NPI of the physician or the eligible professional who ordered or referred the DMEPOS, laboratory, imaging, or specialist services) relating

to written orders or requests for payments for items of DMEPOS and home health, laboratory, imaging, and specialist services. Note that we are clarifying that the documentation includes both written and electronic documentation.

We are revising § 424.535(a)(10) to read, "The Centers for Medicare & Medicaid Services" (CMS) may revoke enrollment, for a period of not more than one year for each act, for a provider or a supplier under section 1866(j) of the Act if such provider or supplier fails to meet the requirements of § 424.516(f). Providers and suppliers will continue to have appeal rights afforded to them in accordance with part 498.

III. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. The NPI requirements set forth in this IFC are necessary to implement the data reporting requirements in section 1128J(e) of the Act, as amended by section 6402(a) of the Affordable Care Act, which require that the Secretary promulgate a regulation to implement this requirement no later than January 2011. Moreover these NPI requirements are needed to implement the Medicare requirements specified in section 6405 of the Affordable Care Act that are effective July 1, 2010. Section 6406 of the Affordable Care Act was effective January 1, 2010. It is imperative that the regulatory provisions be set forth as soon as possible to deliver the guidance necessary to enact the provisions.

In addition, several of these provisions may be issued as an IFC because they fall under the exception in Medicare to the section 1871(b)(1)(B) of the Act rulemaking requirements. Section 1871 of the Act generally requires that we issue a notice of proposed rulemaking prior to issuing a final rule under the Medicare program. However, section 1871(b)(1)(b) provides that the Secretary is not required to issue a notice of proposed rulemaking before issuing a final rule if "* * * a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute in which the deadline is contained." Section 6405 establishes an effective date of July 1, 2010, which is less than 150 days from the date of enactment of this statute. Moreover, section 6406 establishes an effective date of January 1, 2010, which has already passed.

We do not believe that the portions of this rule not exempted from notice and comment rulemaking pursuant to section 1871(b)(1)(B) of the Act add any new burdens for Medicare or Medicaid providers and suppliers. Both Medicare and Medicaid programs generally require unique provider identifiers, and thus delaying this rule is unnecessary. Finally, a delay in implementing these provisions would be contrary to the public interest and to CMS' efforts to reduce and eliminate fraud and abuse in the Medicare and Medicaid programs. For these reasons, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We are providing a 60-day comment period.

V. Collection of Information Requirements

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection included in this interim final rule with comment period will be submitted for emergency approval to the Office of Management and Budget (OMB). The revised information collection requirements associated with 0938–0685, 0938–0931, and 0938–0999 (see sections V.A. and V.D. of this IFC) will not be effective until approved by OMB.

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding National Provider Identifier (NPI) on All Medicare Enrollment Applications and Claims (§ 424.506)

Section 424.506(b)(1) states that providers and suppliers who are eligible for NPIs be required to report their NPIs on their enrollment applications for Medicare. Similarly, § 424.506 (b)(2) states that if providers or suppliers enrolled in Medicare prior to obtaining NPIs and their NPIs are not in their enrollment records, they must submit enrollment applications containing their NPIs.

The burden associated with the requirements in § 424.506(b) is the time and effort necessary for a provider or a supplier to apply for an NPI and the time and effort necessary to report the NPIs on their enrollment applications for Medicare.

Sections § 424.510 and § 424.515 state that providers and suppliers must submit enrollment information on the applicable enrollment application and update, resubmit, and recertify the accuracy of their enrollment information every 5 years. In addition, § 424.516 lists reporting requirements for providers and suppliers. To submit enrollment information for an initial application (even if enrolling solely to order and refer), a change of information, or to respond to a revalidation request, a provider or supplier must complete and submit the applicable CMS–855 enrollment application or complete and submit the enrollment application over the Internet using Internet-based PECOS. Although we are unable to quantify the number, we do not believe that a significant number of physicians and eligible professionals will enroll in Medicare solely to order and refer. The burden associated with the enrollment requirements found in § 424.510,

§ 424.515, and § 424.516 is the time and effort necessary to complete and submit applicable Medicare enrollment applications. While this burden is subject to the PRA, it is currently approved under existing OMB control numbers (OCN). Specifically, the burden associated with obtaining an NPI is currently approved under OCN 0938–0931. The burden associated with submitting initial Medicare enrollment applications and updating Medicare enrollment information to include NPI is approved under OCN 0938–0685 (Applications CMS–855 A, B, I, and R) 0938–1056 (Application CMS–855 S).

Section 424.506(b)(1) states that providers and suppliers who are enrolled in Medicare must report their National Provider Identifiers (NPIs) and the NPIs of any other providers or suppliers who are required to be identified in their claims on all paper and electronic claims that they send to Medicare. The burden associated with this requirement is the time and effort necessary to complete and submit a claim form. While this requirement is subject to the PRA, the associated burden is currently approved under OCN 0938–0999.

B. ICRs Regarding Ordering and Referring Covered Items and Services for Medicare Beneficiaries (§ 424.507)

Section 424.507 states that to receive payment for covered Part A or Part B home health services, the claim must contain the legal name and the NPI of the ordering physician; and to receive payment for covered items of DMEPOS, and certain other covered Part B items or services (excluding Part B drugs), the claim must contain the legal name and the NPI of the ordering or referring physician or eligible professional. The burden associated with these requirements is the time and effort necessary to submit a claim with the required information. While these requirements are subject to the PRA, the associated burden is currently approved under OCN 0938–0999.

C. ICRs Regarding Additional Provider and Supplier Requirements for Enrolling and Maintaining Active Enrollment Status in the Medicare Program (§ 424.516)

Section 424.516(f)(1) discusses the documentation requirements for providers and suppliers. A provider or supplier is required for 7 years from the date of service to maintain and upon request of CMS or a Medicare contractor, provide access to documentation, including the NPI of the physician or the eligible professional who ordered or referred the item or service, relating to written orders or requests for payments for items of DMEPOS and referrals for home health, laboratory, imaging, and specialist.

Similarly, § 424.516(f) discusses the documentation requirements for providers and suppliers. At § 424.516(f)(1), providers and suppliers are required for 7 years from the date of service to maintain and, upon request of CMS or a Medicare contractor, provide access to documentation, including the NPI of the physician or the eligible professional who ordered or referred the item or service, relating to written orders or requests for payments for items of DMEPOS and referrals for home health, laboratory, imaging, and specialist. At § 424.516(f)(2), physicians and eligible professionals are required for 7 years from the date of service to maintain and, upon request of CMS or a Medicare contractor, provide access to written and electronic documentation relating to written orders or certifications for items of DMEPOS and home health, laboratory, imaging, and specialist services, written, ordered, referred by such physician or non-physician practitioner.

The burden associated with the requirements in § 424.516(f) is the time and effort necessary to both maintain documentation on file and to furnish the information upon request to CMS or a Medicare contractor. While the requirement is subject to the PRA, we believe the associated burden is exempt. As discussed in the final rule that was published November 19, 2008 (73 FR 69726), we believe the burden associated with maintaining documentation and furnishing it upon request is a usual and customary business practice and thereby exempt from the PRA under 5 CFR 1320.3(b)(2).

D. ICRs Regarding the Reporting of National Provider Identifier by Medicaid Providers (§ 431.507(b)(5))

Section 431.107(b)(5) states that a Medicaid provider has to furnish its NPI (if eligible for an NPI) to its State agency and include its NPI on all claims submitted under the Medicaid program. The burden associated with the Medicaid requirements in § 431.107(b)(5) is the time and effort necessary for a provider to report the NPIs to the State agency and on claims submitted to the Medicaid program.

We are in the process of revising the information collection requirements contained in OCNs 0938–0685, 0938–0931, and 0938–0999 in accordance with the provisions of this rulemaking. These information collection requirements will be sent to OMB for review and approval in accordance with the emergency procedures of the PRA and will not go into effect until approved by OMB.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS–6010–IFC]

Fax: (202) 395–6974; or E-mail: *OIRA_submission@omb.eop.gov*

VI. Regulatory Impact Analysis

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804 *et seq.*). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts; and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). Virtually all providers and suppliers who wish to enroll in Medicare and Medicaid programs have already obtained NPIs. Most enrolled Medicare and Medicaid providers and suppliers who will be affected by the statutory and regulatory requirements are already meeting those requirements. For example, Medicare providers and suppliers have been reporting their NPIs on their enrollment applications for 4 years and have been using NPIs in their paper and electronic Medicare claims as well as electronic Medicaid claims for 2 years. The majority of suppliers who submit claims for ordered or referred DMEPOS and laboratory, imaging, and specialist services are ensuring that their claims meet the requirements of this IFC. In addition, the majority of Medicare physicians and eligible professionals who order and refer but who do not have approved enrollment records in PECOS are aware of the need to establish those records and many have already submitted their enrollment

applications to Medicare in order to do so. Medicare DMEPOS suppliers and those physicians and eligible professionals who order DMEPOS are already maintaining documentation in accordance with the requirements of this IFC. Other Medicare providers and suppliers who will be required to do so by this IFC are likely already in full or partial compliance as part of their routine business operations. Therefore, we do not believe this rule reaches the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief for small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6.5 to $31.5 million in any one year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this rule will not have a significant economic impact on a substantial number of small entities. We maintain that this final rule would not have an adverse impact on small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $135 million. This rule does not mandate expenditures by either the governments mentioned or the private sector; therefore, no analysis is required. Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

Since this regulation does not impose significant costs on State or local governments, the requirements of E.O. 13132 are not applicable. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

B. Alternatives Considered

Since this final rule is a codification of statutory provisions found in the Affordable Care Act, we did not consider alternatives to this process.

List of Subjects

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 431

Grant programs-health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 1. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 424.506 is added to read as follows:

§ 424.506 National Provider Identifier (NPI) on all enrollment applications and claims.

(a) *Definition. Eligible professional* means any of the professionals specified in section 1848(k)(3)(B) of the Act.

(b) *Enrollment requirements.* (1) A provider or a supplier who is eligible for an NPI must report its National Provider Identifier (NPI) on its Medicare enrollment application.

(2) If a provider or a supplier who is eligible for an NPI enrolled in the Medicare program prior to obtaining an NPI and the provider's or the supplier's NPI is not in the provider's or the supplier's Medicare enrollment record, the provider or the supplier must submit a Medicare enrollment application that contains the NPI.

(3) A physician or an eligible professional who has validly opted out of the Medicare program does not need to submit an enrollment application.

(c) *Claims reporting requirements.* (1) A provider or a supplier who is enrolled in Medicare and who submits a paper or an electronic claim to Medicare include its National Provider Identifier (NPI) and the NPI(s) of any other provider(s) or suppliers(s) who is required to be identified.

(2) A Medicare beneficiary who submits a claim for service to Medicare—

(i) Must include the legal name of any provider or supplier who is required to be identified in that claim; and

(ii) May, if known to the beneficiary, include the National Provider Identifier (NPI) of any provider or supplier who is required to be identified in that claim.

(3) A Medicare contractor will reject a claim from a provider or a supplier if the required NPI(s) is not reported.

■ 3. Section 424.507 is added to read as follows:

§ 424.507 Ordering and referring covered items and services for Medicare beneficiaries.

(a) *Conditions for payment of claims for ordered or referred covered Part B items and services (excluding home health services described in § 424.507(b) and Part B drugs).* (1) *Part B provider and supplier claims.* To receive payment for ordered or referred covered Part B items and services (excluding home health services described in § 424.507(b), and Part B drugs), a provider's or supplier's must meet all of the following requirements:

(i) The Part B items and services must have been ordered or referred by a physician or, when permitted, an eligible professional (as defined in § 424.506(a) of this part).

(ii) The claim from the Part B provider or supplier must contain the legal name and the National Provider Identifier (NPI) of the physician or the eligible professional (as defined in § 424.506(a) of this part) who ordered or referred.

(iii) The physician or the eligible professional who ordered or referred must have an approved enrollment record or a valid opt-out record in the Provider Enrollment, Chain and Ownership System (PECOS).

(iv) If the items or services were ordered or referred by a resident or an intern, the claim must identify the teaching physician as the ordering or referring supplier. The claim must identify the teaching physician by his or her legal name and NPI and he or she must have an approved enrollment record or a valid opt-out record in PECOS.

(2) *Part B beneficiary claims.* To receive payment for ordered or referred covered Part B items and services (excluding home health services described in § 424.507(b), and Part B

drugs), a beneficiary's claim must meet all of the following requirements:

(i) The Part B items and services must have been ordered or referred by a physician or, when permitted, an eligible professional (as defined in § 424.506(a) of this part).

(ii) The claim must contain the legal name of the physician or the eligible professional (as defined in § 424.506(a) of this part) who ordered or referred.

(iii) The physician or the eligible professional who ordered or referred must have an approved enrollment record or a valid opt-out record in the Provider Enrollment, Chain and Ownership System (PECOS).

(iv) If the items or services were ordered or referred by a resident or an intern, the claim must identify the teaching physician as the ordering or referring supplier. The claim must identify the teaching physician by his or her legal name and he or she must have an approved enrollment record or a valid opt-out record in PECOS.

(b) *Conditions for payment of claims for ordered covered home health services.* (1) *Home health provider claims.* To receive payment for ordered, covered Part A or Part B home health services, a provider's home health services claim must meet all of the following requirements:

(i) The Part A or Part B home health services must have been ordered by a physician;

(ii) The claim from the provider of home health services must contain the legal name and the National Provider Identifier (NPI) of the ordering physician;

(iii) The ordering physician must have an approved enrollment record or a valid opt-out record in the Provider Enrollment, Chain, and Ownership System (PECOS); and

(iv) If the services were ordered by a resident or an intern, the claim must identify the teaching physician as the ordering or referring physician. The claim must identify the teaching physician by his or her legal name and NPI and he or she must have an approved enrollment record or a valid opt-out record in PECOS.

(2) *Home health beneficiary claims.* To receive payment for ordered covered Part A or Part B home health services, a beneficiary's home health services claim must meet all of the following requirements:

(i) The Part A or Part B home health services must have been ordered by a physician.

(ii) The claim from the provider of home health services must contain the legal name of the ordering physician.

(iii) The ordering physician must have an approved enrollment record or a valid opt-out record in the Provider Enrollment, Chain, and Ownership System (PECOS).

(iv) If the services were ordered by a resident or an intern, the claim must identify the teaching physician as the ordering or referring physician. The claim must identify the teaching physician by his or her legal name and he or she must have an approved enrollment record or a valid opt-out record in PECOS.

(c) A Medicare contractor will reject a claim from a provider or a supplier for covered services described in paragraphs (a) and (b) of this section if the claim does not meet the requirements of paragraph (a)(1) and (b)(1) of this section, respectively.

(d) A Medicare contractor may deny a claim from a Medicare beneficiary for covered items or services described in paragraphs (a) and (b) of this section if the claim does not meet the requirements of paragraphs (a)(2) and (b)(2) of this section, respectively.

■ 4. Section 424.516 is amended by revising paragraph (f) to read as follows:

§ 424.516 Additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program.

* * * * *

(f) *Maintaining and providing access to documentation.* (1) A provider or a supplier who furnishes covered ordered DMEPOS or referred home health, laboratory, imaging, or specialist services is required to maintain documentation for 7 years from the date of service and, upon the request of CMS or a Medicare contractor, to provide access to that documentation. The documentation includes written and electronic documents (including the NPI of the physician who ordered the home health services and the NPI of the physician or the eligible professional who ordered or referred the DMEPOS, laboratory, imaging, or specialist services) relating to written orders and requests for payments for items of DMEPOS and home health, laboratory, imaging, and specialist services.

(2) A physician who ordered home health services and a physician and an eligible professional who ordered or referred items of DMEPOS or laboratory, imaging, and specialist services is required to maintain documentation for 7 years from the date of the order, certification, or referral and, upon request of CMS or a Medicare contractor, to provide access to that documentation. The documentation includes written and electronic documents (including the NPI of the physician who ordered the home health services and the NPI of the physician or the eligible professional who ordered or referred the DMEPOS, laboratory, imaging, or specialist services) relating to written orders or requests for payments for items of DMEPOS and home health, laboratory, imaging, and specialist services.

■ 5. Section 424.535 is amended by revising (a)(10) to read as follows:

§ 424.535 Revocation of enrollment and billing privileges in the Medicare program.

(a) * * *

(10) *Failure to document or provide CMS access to documentation.* (i) The provider or supplier (as described in section 1866(j) of the Act) did not comply with the documentation or CMS access requirements specified in § 424.516(f) of this subpart.

(ii) A provider or supplier that meets the revocation criteria specified in paragraph (a)(10)(i) of this section, is subject to revocation for a period of not more than 1 year for each act of noncompliance.

* * * * *

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

■ 6. The authority citation for part 431 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act, (42 U.S.C. 1302).

■ 7. Section 431.107 is amended by adding a new paragraph (b)(5) to read as follows:

§ 431.107 Required provider agreement.

* * * * *

(b) * * *

(5)(i) Furnish to the State agency its National Provider Identifier (NPI) (if eligible for an NPI); and

(ii) Include its NPI on all claims submitted under the Medicaid program.

Dated: April 28, 2010.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: April 29, 2010.

Kathleen Sebelius,

Secretary.

Authority: Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program, and Program No. 93.778, Medical Assistance Program.

[FR Doc. 2010–10505 Filed 4–30–10; 4:15 pm]

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