

Health Care Reform Advisory: CMS Kicks Off Program Integrity Rulemaking Process

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On May 5, 2010, the Centers for Medicare & Medicaid Services (CMS) published an interim final rule (IFR) with comment period, implementing certain portions of the Medicare and Medicaid program integrity provisions included in the Patient Protection and Affordable Care Act (PPACA).¹ The IFR is effective July 6, 2010, but interested parties still may submit comments to CMS no later than 5 p.m. on July 6.

NPI Requirements

Over the past ten years, CMS has taken numerous steps to ensure that only qualified individuals and organizations enroll in the Medicare program and maintain Medicare billing privileges.² With respect to the Medicaid program, each state is responsible for implementing its own Medicaid enrollment process, but CMS provides a federal framework for ensuring program integrity and quality care.³

In keeping with CMS's continuing program integrity efforts, the PPACA requires the Secretary of the U.S. Department of Health and Human Services (HHS) to promulgate regulations requiring "all providers of medical or other items or services and suppliers under the [Medicare and Medicaid] programs...that qualify for a national provider identifier to include their national provider identifier on all applications to enroll in such programs and on all claims for payment submitted under such programs."⁴ As noted by CMS, this requirement builds upon a previous Congressional mandate that every "health care provider"⁵ must obtain a National Provider Identifier (NPI), and CMS's current requirement that any claim submitted by a Medicare fee-for-service or Medicaid provider or supplier must include its own NPI as well as that of any provider or supplier mentioned on the claim.⁶ In addition, CMS already requires reporting of the NPI on all Medicare enrollment applications.⁷

The IFR formalizes CMS's existing requirements and also mandates that Medicaid provider agreements require submission of the NPI at 42 C.F.R. § 424.506.⁸ Any Medicare provider or supplier that enrolled before obtaining an NPI must report the NPI if it does not already appear in the enrollment record maintained in the Provider Enrollment, Chain, and Ownership System (PECOS). The IFR authorizes rejection of Medicare claims that do not include the required NPI(s).⁹ Moreover, a Medicare beneficiary who submits a Medicare claim must include the legal name and NPI of the applicable provider or supplier who rendered services, but can provide just the legal name if the NPI is unknown.¹⁰

Ordering and Referring Certain Covered Items and Services

Exercising discretion granted to the Secretary of HHS by the PPACA, CMS published a new regulation (42 C.F.R. § 424.507) establishing that, as of July 1, 2010, a provider or supplier may receive payment for Part B items and services (excluding home health services, which are addressed elsewhere in the regulation, and Part B drugs) only if ordered or referred by a physician or eligible professional who has an approved enrollment record or valid opt-out record in PECOS.¹¹ As noted, a separate subsection addresses covered Part A or Part B home health services, which must be ordered by a physician who meets the same qualifications.¹² All claims for services provided by laboratories, imaging suppliers, specialists, and home health agencies must contain the legal name and NPI of the ordering or referring physician or eligible professional.¹³ Otherwise, the Medicare contractor will reject the claim.¹⁴

Although the PPACA mandated these changes with respect to DME and home health services only, it gave the Secretary of HHS broad authority to extend the requirement to all other Medicare services, including covered Part D drugs.¹⁵ CMS made clear in the IFR that it reserves the right to expand the regulation to cover additional services and that it will issue a proposal applicable to Part B drugs as early as next year.¹⁶

CMS cited several underlying reasons for these changes. First, the rule will ensure that Medicare beneficiaries receive high-quality health care items and services because CMS will have the opportunity to verify the credentials of the ordering or referring provider or supplier.¹⁷ Second, the rule will help reduce Medicare program vulnerability by giving CMS the ability to tie specific Medicare claims to the ordering or referring physician or professional.¹⁸ Finally, the rule will allow CMS to establish claims edits, as appropriate, to “check for over-ordering specific items or services, over-referring specific services, and over-ordering or over-referring to specific providers of services and suppliers.”¹⁹

Physicians and eligible professionals who do not ordinarily enroll in the Medicare program may need to take certain steps to ensure claims are approved. For example, the relatively few physicians who have elected to opt out of the Medicare program must have a properly filed affidavit on file with the Medicare contractor to ensure that an enrollment record is in PECOS.²⁰ Additionally, dentists and pediatricians, who typically do not provide Medicare-covered services or who have a low volume of Medicare-eligible patients, also must establish an approved enrollment record.²¹

Maintenance and Access to Documentation

The PPACA authorizes revocation of enrollment for up to one year **for each act** for a physician or supplier based on the failure to maintain and allow access to documentation relating to written orders or requests for payment for DME, certifications for home health services, or referrals for other items or services written or ordered by the physician or supplier on or after January 1, 2010.²² Providers of services also have an obligation to maintain and provide access to such documentation.²³

To implement these statutory provisions, CMS has expanded 42 C.F.R. § 424.516(f), which already requires providers and suppliers to maintain ordering and referring documentation as a condition of enrollment, by requiring maintenance and access to documentation related to orders and referrals for covered home health, laboratory, imaging, and specialist services.²⁴ Such documentation must be maintained for a period of seven years from the date of service.²⁵ The IFR also proposed revisions to 42 C.F.R. § 424.535(a)(10) to provide for revocation of enrollment for a period of not more than one year for each act.²⁶

Conclusion

Given that the IFR authorizes rejection of Medicare claims that do not include the required NPI(s) or that do not contain the legal name and NPI of the ordering or referring physician or eligible professional, providers and suppliers should immediately consider whether changes to current billing policies and procedures are necessary to comply. Further, in light of the substantial penalties that may result from the failure to maintain and allow access to ordering and referring documentation, providers and suppliers should assess whether its records management policies and procedures are sufficient.

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Endnotes

¹ Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements, 75 Fed. Reg. 24,437 (published May 5, 2010) (to be codified at various sections of 42 C.F.R. Parts 424 and 431) (available at: <http://edocket.access.gpo.gov/2010/pdf/2010-10505.pdf>).

² 75 Fed. Reg. 24,438-39.

³ *Id.* at 24,439.

⁴ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6402(a) (2010) (“PPACA”), *codified at* Social Security Act (“SSA”) § 1128J(e).

⁵ The term “health care provider,” as used in the Health Insurance Portability and Accountability Act, includes all providers and suppliers eligible to enroll in the Medicare program and most who are eligible to enroll in the Medicaid program. *See* 75 Fed. Reg. 24,439; *see also* 45 C.F.R. § 160.103.

⁶ 75 Fed. Reg. 24,439.

⁷ *Id.*

⁸ 42 C.F.R. § 424.506(b).

⁹ 42 C.F.R. § 424.506(c)(3).

¹⁰ 42 C.F.R. § 424.506(c)(2).

¹¹ 42 C.F.R. § 424.507(a)(1).

¹² 42 C.F.R. § 424.507(b)(1).

¹³ *See* 42 C.F.R. § 424.507(a)(1)(ii), (b)(1)(ii).

¹⁴ 42 C.F.R. § 424.507(c).

¹⁵ *See* PPACA § 6405(c) (2010).

¹⁶ 75 Fed. Reg. at 24,443.

¹⁷ *Id.* at 24,444.

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ 75 Fed. Reg. at 24,443.

²¹ *Id.* at 24,444.

²² PPACA § 6406 (2010), *codified at* Social Security Act §1866(a)(1)(W).

²³ *Id.*

²⁴ 75 Fed. Reg. at 24,445.

²⁵ 42 C.F.R. § 424.516(f)(1).

²⁶ 42 C.F.R. § 424.535(a)(10).

For further information regarding this or any issue related to Health Care Reform, please contact one of the professionals listed below or the Mintz Levin attorney who ordinarily handles your legal affairs.

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