



June 29, 2010

Submitted electronically to <http://www.regulations.gov>

Centers for Medicare and Medicaid Services

Department of Health and Human Services

Attention: CMS-6010-IFC

PO Box 8013

Baltimore, MD 21244-8013

RE: CMS-6010-IFC - *Interim Final Rule with Comment Period: Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements*

The Food Marketing Institute (FMI) which represents approximately 26,000 retail food stores and 14,000 pharmacies is writing to submit our comments on the Centers for Medicare and Medicaid Services (CMS) Interim Final Rule with comment period, CMS-6010-IFC set to become effective July 6, 2010 ("IFC").

The notice provides that the IFC implements several provisions in the Patient Protection and Affordable Care Act of 2010 ("PPACA") relating to the requirement that providers and suppliers include their National Provider Identifier (NPI) on Medicare enrollment applications as well as on Medicaid provider agreements and on claims for payment under such programs. In addition, the IFC requires the NPI of the physicians and eligible professionals who order or refer the covered items and services to be on the claim. Additionally, the IFC adds the requirement that payment of claims is conditioned on the ordering or referring physician or eligible professional having an approved enrollment record (or valid opt-out record) in the Medicare Provider Enrollment, Chain and Ownership System (PECOS). The IFC also adds requirements for maintaining required documentation.

FMI thanks CMS for working with us, the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) over the past months on issues related to the implementation of the Phase 1 and Phase 2 edits for the PECOS system. We also believe that the implementation delay until January 3, 2011 of the Phase 2 edits that CMS issued earlier this year is essential and should be maintained. The Phase 2 delay is crucial in order to give providers the additional time needed to enroll and/or update their PECOS records. It would also give CMS the opportunity to make any necessary adjustments to help assure that the implementation was the least disruptive for beneficiaries.

We are very concerned with the accelerated date for implementation. In particular, we are concerned with likely disruptions in beneficiaries being able to obtain their medical equipment and services from pharmacies due to lack of provider enrollment in PECOS -- which remains significant -- and is a matter that is outside the control of pharmacy. Because provider enrollment in PECOS can take many days (perhaps up to 60 days) and because there are little to no incentives for providers to enroll, the lack of provider enrollment will likely not be easily or quickly remedied. As a result, beneficiaries could be forced to see another provider that is enrolled to obtain their Part B items and services, adding costs to the healthcare system.

Likewise, we are dismayed that these circumstances unfairly put suppliers at risk for the claims being denied if the provider is not enrolled in PECOS. Yet, there is no corresponding risk on the provider for not enrolling or an incentive for providers to enroll. Currently, our members are seeing rejections for up to 30% of claims due to providers not having proper enrollment in PECOS, a staggering number when one considers the potential disruption for beneficiary access. As a result, if a pharmacy receives a prescription for a beneficiary and the prescriber is not properly enrolled in PECOS but advises that they will enroll or update their enrollment, the pharmacy would have to hold the claim until the provider is enrolled. If the prescriber fails to enroll or update his or her enrollment properly, the beneficiary's access to needed Part B items and services is disrupted.

We are also concerned with the potential for pharmacies (while trying to help patients obtain their needed medical equipment and supplies) to be inadvertently subject to a false claim issue, through no fault of their own. For example, a supplier could inadvertently submit a claim that was ordered or referred by a physician who indicates that they are enrolled in PECOS or unknown to the supplier is not enrolled properly in PECOS and the supplier then receives payment. These present circumstances that may place the supplier at risk through no fault of their own.

In March, before publication of this IFC, we wrote to CMS with our concerns over PECOS implementation. Now, with the implementation being moved up six months to July 6th on extremely short notice without resolution of the outstanding issues, we have even stronger concerns. Below we discuss our concerns and offer our recommendations.

CMS should maintain the January 3, 2011 date for Phase 2 implementation

We believe that CMS has the authority to maintain the January 3, 2011 deadline for the Phase 2 edits and be in compliance with the health care reform law. Section 6405 of the PPACA relating to enrollment of physicians or eligible professionals has an effective date of on or after July 1, 2010. As such, we believe that CMS has the discretion under the PPACA to have continued with the January 3, 2011 implementation of the Phase 2 edits for provider PECOS enrollment. We believe that this is essential considering (i) the likely disruptions for beneficiary access to medical equipment and supplies, (ii) the additional time needed by providers and suppliers to prepare, (iii)

the lack of granularity of claims edits to advise suppliers of the PECOS enrollment status of the physician or eligible professional and the particular reason for a rejection such as a name mismatch, and (iv) the significant number of physicians and eligible professional that are not properly enrolled in the PECOS system.

Unworkable requirement for teaching physicians to be on claims for the intern or resident issuing the prescription:

The requirement for teaching physicians to be named on the claim as the ordering or referring provider for prescriptions written by interns and residents will be operationally and administratively impossible for pharmacy suppliers to administer.

Interns and residents who have prescribing authority write the prescriptions for the patients they see, not the teaching physician. Accordingly, the intern or resident will be on the prescription as the prescriber, not the teaching physician. Naming the teaching physician presents a huge problem for pharmacies in dispensing and billing for these prescriptions. Pharmacies must indicate the issuing prescriber on the prescription container label (i.e. the intern or resident). The prescriber is the name that is identified with the prescription in the pharmacy computer system and associated with the claim. Pharmacies cannot indicate a prescriber different from the one who wrote the prescription. However, the new requirement to indicate the teaching physician on the claim would require pharmacies to substitute another prescriber for the prescriber who actually wrote the prescription. This will be operationally impossible and out of compliance with the requirements placed on pharmacies under state pharmacy laws and regulations to indicate the prescriber who issued the prescription.

Another significant problem is the difficulty in identifying the teaching physician. The teaching physician will need to be identified by the intern or resident. However, interns and residents move frequently among rotations making it difficult if not impossible to locate them. As a result, Part B patients may face delays in obtaining their Part B items and services or may not be able to obtain them at all, leading to concerns over their health care.

PECOS enrollment concerns

Our members are informing us that they are seeing a significant number of error codes and claims rejections – up to 30% -- related to the lack of physicians and eligible professionals having proper enrollment in PECOS or some other PECOS related issue. Such issues are not merely a matter of repeat rejections for the same providers; but are seen regularly by pharmacies among all providers.

Pharmacies have done outreach to physicians and eligible professionals relative to PECOS enrollment issues and found that many are unaware of the need to enroll in PECOS or to update

their enrollment record. Moreover, the considerable time required for registration and completion of the PECOS enrollment process will likely delay provider enrollment information reaching CMS and providers being properly enrolled. These delays will significantly affect the ability of suppliers to provide services to Part B beneficiaries leading to service disruptions.

All of these difficulties pose key barriers to successful deployment of the PECOS program under this shortened implementation – six months earlier than expected -- and to suppliers being able to provide items and services to beneficiaries. Such circumstances will likely result in suppliers having no recourse and being unable to provide Part B items and services to the beneficiary until the PECOS matter is resolved by the provider.

Concerns with requirement for legal name

We also have concerns with the requirement to have the legal name of the physician or eligible provider on the claim. Providers often use a variation of their legal name (e.g. Bob instead of Robert) on their prescription pads and/or in signing their name on the prescription. The name that appears on the prescription is the name used by pharmacies for entering and dispensing the patient's prescription and is the name the patient recognizes. Providers are not required to use their legal name on their prescription pad or when signing the prescription.

In addition, providers are required to have an NPI, and the NPI number is used as the identifier on the claim. The NPI should be more than sufficient for identifying the particular provider without need for the legal name. We therefore ask that this requirement be removed.

Provide suppliers and claims processors with access to the daily updated PECOS file in a readily useable and readable electronic format

We remain concerned that the current PECOS information available to suppliers and claims processors in the pdf format does not provide timely and current information on PECOS enrollment. As a result suppliers and claims processors lack the current timely information that they need to determine whether a provider is properly enrolled in PECOS or what the exact problem is with the PECOS enrollment e.g. is it a name mismatch or another issue. This places pharmacy suppliers in the untenable position of not knowing whether it is proper to proceed with or deny a claim, all the while knowing that the beneficiary needs access to their medical equipment and supplies for care and treatment.

In addition, suppliers and claims processors do not have access to a PECOS file that is in a useable readable electronic format. The pdf version of the file is difficult to work with. It cannot be readily translated into a readable format and the translation process is likely to result in confusing or misleading information about provider enrollment

Although, we understand that the Common Electronic Data Interchange (CEDI) has access to a PECOS file that is updated nightly, the PECOS file made available to suppliers or processors is only updated “periodically.” We ask that that CMS make a current PECOS enrollment file publicly available on a nightly basis and in a readily useable and readable electronic format such as an Excel file or Microsoft Office Access file. Without current PECOS information at the point of sale, suppliers will be hindered in their ability to make timely dispensing decisions, which will undoubtedly lead to delays in beneficiaries receiving prescribed items and services.

Provide enhanced granularity in CEDI error codes

We have concerns with the lack of granularity of the CEDI error codes for claims rejections. The same CEDI error code is provided regardless of whether the issue is proper enrollment in PECOS or a data mismatch such as a name mismatch between the claim and the PECOS enrollment file. We are asking that more granular error codes be provided to give suppliers information they need for a more efficient resolution of any claims that are rejected. This should help in reducing the cost burden that providers and suppliers are likely to experience as a result of the PECOS implementation and assist with minimizing disruptions in beneficiary access to items and services.

Give pharmacies sufficient time to re-bill claims

In view of the significant number of claims rejections experienced by pharmacies – up to 30% - from PECOS issues (over which pharmacies have little to no control), it is imperative that pharmacies be given sufficient time to resolve the error and re-bill the claim. Many claim rejections may be due to data mismatch between the claim and the PECOS enrollment file. Because resolution of these problems will likely take considerable time and require action by physicians and eligible professionals, matters outside the control of pharmacies, we ask CMS to permit suppliers to re-bill claims denied due to the PECOS edits for up to one year, and not apply the truncated 120 days normally provided for “denied” claims.

Conclusion

To lessen disruption in beneficiary access to items and services and address the concerns discussed above, we respectfully ask that CMS use its discretion to move implementation back to January 3, 2011, *at the earliest*, to allow sufficient time for physicians and eligible professionals to enroll or update their enrollment records in PECOS so that they have an approved record. In addition, we strongly recommend that CMS engage in a more aggressive outreach campaign to educate physicians and eligible professionals regarding the need to immediately enroll in PECOS and/or update their PECOS enrollment record. We also ask that the requirement for teaching physicians to be on the claim be removed.

We also respectfully ask CMS to address the following: (1) streamlining the PECOS system enrollment process for providers and suppliers; (2) providing suppliers and claims processors with

the PECOS enrollment files on a daily basis, rather than “periodically” and providing it in a readily useable and readable electronic format as this will help pharmacies and processors with claims processing and point of sale determinations; (3) working with CEDI to implement additional granularity on the current error codes and adding new error codes that will give suppliers the information the need for efficient resolution of claims issues and to make point of sale dispensing determinations; (4) removing the requirement for use of the legal name as prescribers are identified through their NPI and pharmacies receive prescriptions with the name used by the prescriber which may not be the legal name; and (5) providing pharmacies with sufficient time to rebill claims in view of the significant enrollment issues.

We thank you for consideration of our recommendations which are offered to minimize service disruptions for beneficiaries and for the supplier and provider communities.

Sincerely,



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