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For Hospitals, Laboratories and Physician Practices

A New Era Of HIPAA Enforcement Begins

The Health and Human Services Office of Inspector General (OIG) has begun auditing covered entities for compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) security rule.

The audits began in March at Piedmont Hospital in Atlanta, the first hospital provider in the country to undergo such an audit, according to a healthcare advisory issued by the law firm of Alston & Bird (Washington, D.C.).

In addition, Secretary of Health and Human Services Mike Leavitt on April 16 delegated to the director of the Office for Civil Rights (OCR) the authority to issue subpoenas in investigations of alleged violations of the HIPAA privacy rule.

Together, these two events represent something of a surprise in enforcement of the HIPAA privacy and security rules, the advisory notes.

Privacy Rule Enforcement

The Office for Civil Rights has enforced the HIPAA privacy rule since its effective date in 2003—largely based on a voluntary compliance approach with complaint-driven investigations. Unofficial reports claim that OCR received approximately 24,000 complaints from 2003 through 2006, over 75% of which have been closed, notes the Alston & Bird (A&B) advisory.

Fewer than 40 complaints have been accepted by the Department of Justice for further investigation or prosecution. To date, no OCR-initiated *Cont. on p. 2*

United Clarifies Lab Network Policy

United Healthcare has clarified some troubling provisions in its new policy requiring all participating physicians and healthcare professionals to refer laboratory services only to an in-network provider, according to the College of American Pathologists (CAP).

Under United's new policy, providers will be penalized if they make referrals to nonparticipating laboratories by imposing a financial penalty, decreasing payments to the provider, changing reward eligibility and premium designation, or terminating the provider's contract.

In response to a March 21 letter that CAP sent to a senior vice president at United, the company has clarified that it will "take action with respect to laboratory referrals *Cont. on p. 10*

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investigations have taken place (absent a private complaint), and no fines have been levied against covered entities by OCR for privacy rule violations.

"However, covered entities should be prepared," warns A&B. "The April 2007 delegation of subpoena power may result in a more proactive enforcement of the privacy rule in the near future."

Security Rule Enforcement

OCR's counterpart for the enforcement of the HIPAA security rule is the Centers for Medicare and Medicaid Services (CMS). CMS has not investigated providers proactively for compliance with the security rule since its effective date in 2005. "Perhaps concerned about security rule enforcement, however, the OIG has begun its security rule audit of healthcare providers," says the advisory.

The OIG hinted at the new enforcement effort in its 2007 OIG Work Plan, noting that its Office of Audit Services would review experience with the HIPAA privacy and security rules to identify key issues that may be relevant to HHS's health information technology initiative. This initiative is designed to foster the use of electronic medical records throughout the health industry.

"It appears that, with electronic medical records on the action item list of CMS and with efforts underway at most major health systems to convert to electronic records systems, the OIG is concerned that the IT systems that will house these records must be secure and must be operated in compliance with the security rule," says the advisory. As further evidence of the concerns, CMS on Dec. 28, 2006, published guidance on the security rule, "HIPAA Security Guidance for Remote Use of and Access to Electronic Protected Health Information."

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— Alston & Bird

Recent months also have seen a significant number of information security breaches involving electronic protected health information (PHI). Many of these have involved lost or stolen laptop computers with inadequate security. "These security incidents are no doubt the reason that CMS issued its guidance on remote access to electronic PHI," says A&B. "The OIG audit initiative presumably represents another reaction by the government to a growing concern over the security of health information."

What exactly does the security rule require of covered entities? Although complex and technical, the security rule first requires that a "risk assessment" be undertaken by the covered entity to assess thoroughly the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic PHI maintained by the covered entity. The security rule also requires the covered entity to take certain steps to ensure that risks of improper use or disclosure of electronic PHI are minimized.

Particularly where PHI is accessed or transmitted by means of remote devices or via the Internet, reasonable safeguards must be implemented to prevent unauthorized access or disclosure of electronic PHI. In all, there are more than 40 standards with which the entity must comply. The covered entity must meet all of the security rule's "required standards" as noted in the rule and should assess in writing the reasonableness and applicability of the rule's "addressable specifications."

"Documentation is key to HIPAA security compliance," notes the advisory. "With audits of security compliance underway by the OIG, every covered entity is well-advised to review its HIPAA security program and verify that its compliance with the HIPAA security rule is well documented."

Florida Lab Owner Sentenced To Jail For Fraud

The owner of two South Florida medical laboratories April 18 was sentenced to nearly five years in prison in connection with a $2.5 million Medicare billing scheme, federal prosecutors announced (*United States v. Serrano*).

In addition to the 57-month prison term, defendant Marcelo De Jesus Serrano also was to forfeit more than $2.8 million in cash and stock holdings, as well as three Mercedes-Benz automobiles and a motorcycle, R. Alexander Acosta, U.S. attorney for the Southern District of Florida, said in a written statement.

The sentencing followed Serrano's January guilty plea agreement, filed in U.S. District Court for the Southern District of Florida, to one healthcare conspiracy count.

The prosecution stemmed from a 2003-2005 billing scheme from two Hallandale Beach clinical laboratories, Biocyte Laboratories Inc. and Washington Medical Laboratory Inc., operated by Serrano, the statement said.

"To conceal his ownership interests in the labs, Serrano incorporated the labs with the State of Florida in the names of fake owners, including a deceased nursing home patient," the statement said. "Serrano then submitted in excess of $5 million in claims to the Medicare program for fraudulent clinical laboratory testing."

The government was represented by Special Assistant U.S. Attorney William J. Parente Jr., Southern District of Florida, Miami. Serrano was represented by Ruben Oliva, Rojas & Oliva, Miami, and Vincent Joseph Flynn, Miami.

CMS Pilot Projects Find Connection Between Compliance, Improved Claims

Healthcare compliance officers are getting proof from the Centers for Medicare & Medicaid Services (CMS) that effective corporate compliance programs can improve claims accuracy.

CMS Program Integrity Group Director Kimberly L. Brandt on April 23 said the agency in June would release a comprehensive report with findings from its three-year, 16-hospital compliance effectiveness pilot project that found a connection between effective organizational communication at hospitals and improved claims accuracy. Accuracy is key for prompt and correct payments of providers, she said.

"The bottom line is compliance works," Brandt told attendees at the Healthcare Compliance Association Compliance Institute, where she and CMS Program Integrity Group health insurance specialist Lisa J. Eggleston released initial findings from the pilot.

CMS recruited hospitals to participate in the pilot project to determine whether and to what extent compliance programs affected claims accuracy, Brandt and Eggleston said.

As part of the pilot, Eggleston said, CMS provided the participating hospitals with claims data they otherwise would not have received, such as the number and type of contractor and provider-initiated adjustments and specific details about claims denials and returns.

Hospitals used the data to identify claims processing weaknesses and address them in their compliance programs. Participants also shared information with one another throughout the process, Eggleston said.

Brandt said a key finding was that when hospitals improved the lines of communication between the auditing/monitoring and training/education departments, statistically valid improvements in claims

submissions were noticed. The reason, she said, was because hospitals used auditing results to identify weaknesses in claims processing, and then shaped training programs to address those weaknesses.

Eggleston said that, from a research perspective, participating hospitals had significant improvements in two outcome areas, contractor-initiated adjustments and provider-initiated adjustments.

"These savings can result in cost savings to providers and to CMS," Eggleston said.

Brandt and Eggleston noted that it was unlikely CMS could provide the same detailed claims data to all providers as it did to the pilot project hospitals. However, Eggleston said it might be possible for providers to do their own data analysis to find the same kinds of trends, and then shape their compliance programs to address any deficiencies.

Brandt said the findings are useful for all compliance officers because the data give them proof to take to their boards of directors and corporate leaders to justify budget and resource needs for compliance programs.

OIG Recommends Improved Training For Contractors

Updated training for Medicare Part A contractors could ensure a better understanding of policies for processing provider applications, the Department of Health and Human Services Office of Inspector General said in an April 12 report on early implementation of the Provider Enrollment, Chain and Ownership System (PECOS).

The OIG found that, as of July 31, 2005, most applications classified by Part A contractors as exceeding the application time frame had not actually exceeded it, according to the report, "Provider Enrollment, Chain and Ownership System: Early Implementation Challenges" (OEI-07-05-00100).

"The misclassification was due to the fact that contractors retained applications awaiting tie-in notices in pending inventory or failed to update the record status in the PECOS correctly," the OIG said in explaining the problem.

PECOS is a repository of Medicare provider enrollment records and is the primary source of provider enrollment information and the "frontline defense to keep fraudulent providers from participating in Medicare," the OIG said.

Although PECOS was expected to reduce the processing time for provider enrollment applications, implementation problems in 2002 caused delays in processing applications early on.

In addition to issues identified among Part A contractors, the OIG found that applications exceeding time frames among Part B contractors were largely attributable to backlogs reported by one contractor and the failure of providers to respond to requests for information.

The OIG also found that more than 60% of contractors experienced problems accessing PECOS, reporting that they "received frequent, intermittent notices from CMS asking them to use PECOS only during certain time periods." Contractors also said they had trouble obtaining and rectifying user IDs with PECOS access for their employees.

CMS responded to the report saying that many of the PECOS start-up issues already had been resolved, but that the findings would be useful in ongoing management of the system.

The Medicare agency indicated it had worked with Part A contractors on training issues, and that it had begun working on improving system capacity for PECOS.

The report is available at *www.oig.hhs.gov/oei/reports/oei-07-05-00100.pdf*.

COMPLIANCE PERSPECTIVES

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Two Steps Forward, One Step Back: A Review Of Proposed Clinical Trial Policy

On April 10, 2007, the Centers for Medicare and Medicaid Services (CMS) released proposed revisions to the existing national coverage decision setting forth the circumstances under which Medicare would pay for routine care costs provided during the course of a clinical trial. The coverage decision was issued on Sept. 19, 2000, in response to then President Clinton's June 7, 2000, executive memorandum promoting the participation of Medicare beneficiaries in clinical trials. Participation in clinical trials affords subjects access to emerging medical technologies and treatment protocols and is an important medical opportunity for the nation's Medicare community.

The goals of the proposed revisions were to clarify a) the attributes of clinical trials eligible for Medicare beneficiary participation; and b) the types of costs eligible for reimbursement. The proposed "Clinical Research Policy" (CRP) provides greater specificity and clarity—a significant step forward. The proposed CRP, however, in a concerning step backward, may also inadvertently restrict the types of clinical trials eligible for reimbursement—particularly in the areas of cancer research—thereby running counter to the philosophical underpinnings of the rule. The public has 30 days to comment and the agency is expected to issue a final rule approximately 60 days thereafter, or around July 9, 2007.

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Background

The linchpin of Medicare coverage is that it pays for "medically necessary" services. Beyond all of the specific exclusions, coverage clarifications, and reimbursement rates, medically necessary means, essentially, those items and services that the medical community provides as part of the day-in, day-out standard of care that are reasonably required to diagnose or treat a specific health condition. As a result, items and services provided during the course of a clinical trial—which, by definition, involve something investigational in nature—could systematically fall outside of the realm of medically necessary without further statement by the Medicare program.

Uncertainty as to whether Medicare would cover routine costs incurred during a clinical trial functioned as a financial barrier to the participation of Medicare enrollees in the research arena.[1] The systematic under-representation of Medicare beneficiaries in clinical trials has at least two significant negative effects. First, the Medicare population is a distinct demographic population—generally, people

[1] Prior to 2000 Only about 1% of elderly Americans participated in clinical trials of drugs and treatments even though the elderly are more severely affected by disease than are younger people. Further, 73 percent of cancer patients are older than 65 but people that age make up only 33% of those enrolled in clinical trials. Medicare to Expand Clinical Trial Coverage, (2000), *www.archives.cnn.com/2000/ALLPOLITICS/stories/06/07/clinton.medicare/index.html* (last visited April 30, 2007).

over the age of 65. Given the much-touted "baby boomer" generation, the scientific community needs to understand how medical interventions work (and don't work) in older people. Researchers have long been concerned about the chronic absence of certain medically relevant communities—women, children, etc.—from research data.[2]

Although there may be many reasons why the over 65-population might not consistently participate in clinical research, financial barriers only compound disincentives for research participation. If the particular effects of a treatment protocol, drug, or drug regimen on older patients are not well documented, physicians are left with an incomplete data picture on which to base their medical decision-making. If there are poorly understood and anticipated negative outcomes for older Americans, the over 65-population may experience more adverse events, poorer response rates, and an overall diminished prognosis, necessitating more medical interventions, and thereby increasing Medicare claims in the process. To put it differently, a nickel of prevention may be worth a dollar of cure.

Second, in certain cases, patients who decide not to, or cannot, participate in research are not meaningfully disadvantaged because participation or lack thereof in the particular research study does not significantly affect health outcomes (for example, a trial in which two different dosing regimens are being compared to improve patient convenience). In these situations, the individual can still receive medically appropriate and effective care outside of a clinical trial.

In many other situations, however, the most promising medical approach may be investigational. In those cases, financial barriers to participation have a material and deleterious impact on a patient's health. For example, in the oncology arena, individuals frequently participate in clinical trials because they have not responded to standard of care treatments or are otherwise medically unable to undergo the standard of care treatment approach. Since cancer rates increase as we age, the need to participate in clinical research is compounded in the Medicare population.[3]

If those individuals decide against participating in clinical trials because a significant portion of the care would not be covered by Medicare and they cannot afford to pay for the care themselves, they may not have access to the one or two experimental treatments that offer the best chance for extended survival or recovery. For these patients, the investigational intervention is the "medically necessary" care, and thus, a comprehensive national commitment to underwriting the costs of the Medicare population's participation is critically important.

2000 NCD

The 2000 Medicare National Coverage Decision (NCD) dealt primarily with drug trials. As a practical matter, coverage for investigational devices was principally determined by the Food and Drug Administration's (FDA) designation of so-called Part A and Part B devices, with routine care costs covered for Part B devices. For the qualifying clinical trials, Medicare would cover "routine" costs. This translated, generally, into Medicare not paying for the specific investigational test article, but paying for those items and services that would have been provided regardless if the patient would have received standard of care.

[2] See, e.g., National Institutes of Health, NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research, PHS Grant Application (PHS 398), *grants.nih.gov/grants/funding/phs398/instructions2/p3_nih_policy_women_and_minorities.htm* (last visited April 30, 2007).

[3] Advancing age is a high-risk factor for cancer, with persons over-65 accounting for 60% of newly diagnosed malignancies and 70% of all cancer deaths. Nathan A Berger, M.D., et. al., Cancer in the Elderly, 117 Trans. Am. Clin. Climatological Assoc. 147 (2006) (The age-adjusted cancer incidence rate is 2151/100,000 population for those over 65 compared to 208/100,000 for those under 65.)

The 2000 NCD was criticized, for among other reasons, because: a) the self-certification standards were never announced; b) there was confusion about what costs constituted "routine" costs; and c) the 2000 NCD included an ambiguous provision disqualifying services paid for by sponsors and did not address the Medicare Secondary Payor Rule's applicability to clinical research, which was seen as a barrier to industry sponsors agreeing to cover costs that were denied by insurance. On July 10, 2006, CMS announced that it would revisit the 2000 NCD, and the proposed policy is the result of that process.[4]

CMS identified 10 issues that it would address in revising the 2000 NCD:

1 Clarify the payment criteria for clinical costs in research studies other than clinical trials;

2 Devise a strategy to ensure that Medicare-covered clinical studies are enrolled in the NIH clinical trials registry Web site;

3 Develop criteria to assure that any Medicare covered clinical research study include a representative sample of Medicare beneficiaries by demographic and clinical characteristics;

4 Clarify the definitions of routine clinical care costs and investigational costs in clinical research studies including clinical trials;

5 Remove the self-certification process that was never implemented;

6 Clarify the scientific and technical roles of federal agencies in overseeing IND-exempt trials;

7 Determine if coverage of routine clinical care costs is warranted for studies beyond those covered by the current policy;

8 Clarify how items/services that do not meet the requirements of 1862(a)(1)(A) but are of potential benefit can be covered in clinical research studies as an outcome of the NCD process;

9 Clarify whether and under what circumstances an item/service non-covered nationally may be covered in the context of clinical research to elucidate the impact of the item or service on health outcomes in Medicare beneficiaries; and

10 Discuss Medicare policy for payment of Humanitarian Use Device (HUD) costs.

Proposed CRP

The Proposed CRP is designed to continue the governmental commitment to enabling Medicare enrollees to participate in clinical trials while clarifying those situations in which Medicare will foot the bill for routine costs and services. Although the proposed CRP makes a number of changes, certain features deserve particularly close attention, including:

❖ The proposal changes the name of the policy to the "Clinical Research Policy" to "signal [CMS's] continued support of beneficiaries' participation in the full range of qualified, scientifically sound research projects."

❖ The proposed CRP provides a definition of research. Of interesting note, it does not incorporate the definition of "research" found in the primary federal regulation governing clinical research known as the "Common Rule."

❖ The proposed CRP seeks to clarify "routine costs," which were covered under the 2000 NCD by replacing it with the term "routine clinical services," "investigative clinical services," and "administrative services."

❖ The proposed CRP continues the two-part approach of the 2000 NCD, dividing such standards into "scientifically and technically sound general study standards" and "Medicare-specific standards." The former are the characteristics of a well-designed, scientifically bona fide study. The latter are the particular stan-

[4] Centers for Medicare and Medicaid Services, NCA Tracking Sheet for Clinical Trial Policy (CAG-00071R), *www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=186* (last visited April 30, 2007).

dards to qualify for Medicare reimbursement. In other words, a study may be bona fide and scientifically appropriate, but still not eligible for Medicare reimbursement if the study does not further the specific funding goals of the CRP.

❖ As in the 2000 NCD, the proposed rule seeks to identify a mechanism by which CMS can guarantee that the standards just described are met. The proposed CRP, therefore, continues to identify those clinical trials with sufficient federal supervision that CMS can feel reasonably confident that the standards are met. Such trials are deemed to qualify for Medicare reimbursement ("approved studies"). In a significant departure from the 2000 NCD, however, the proposed rule eliminates any other mechanism for interested parties to demonstrate the scientific bona fides of a proposed research study to qualify it for Medicare reimbursement.

Understandably, CMS did not embrace continuing the self-qualifying mechanism under the 2000 NCD, fearing that it was subject to ambiguity and/or abuse. But, consistent with the public policy intent to make clinical trial participation opportunities available to Medicare beneficiaries, CMS should consider providing for another route whereby interested parties (for example, the research site, sponsor, and/or investigator) can request that an objective, independent body review the study to determine whether it meets the scientifically and technically sound general study standards or otherwise presents an important, therapeutic opportunity for Medicare beneficiaries, and therefore should qualify for reimbursement. If CMS declines to provide for this alternative pathway, CMS may limit considerably the universe of qualifying trials.

The proposed CRP is designed to continue the governmental commitment to enabling Medicare enrollees to participate in clinical trials while clarifying those situations in which Medicare will foot the bill for routine costs and services.

❖ Further narrowing the range of clinical research eligible for Medicare reimbursement, the proposed CRP proposes to exclude investigational new drug (IND) application-exempt studies from the deemed approved studies. Under the 2000 NCD, clinical trials that were ruled IND-exempt by the FDA were still deemed as qualifying trials. The proposed CRP eliminates this category.

Thus, if the FDA determines that a clinical trial does not require an IND, the trial becomes ineligible for Medicare reimbursement. This is particularly ironic since one of the requirements for obtaining an FDA IND-exemption is a demonstration that the investigation "does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the product." [5] In order words, the less "investigational" a study is (i.e., the more akin to standard of care), the less likelihood of coverage. Such a result seems inconsistent with the goals of the policy.

❖ The proposed CRP states that "Medicare does not cover routine clinical services when they are provided free to the Medicare beneficiary or when the study sponsor agreement with investigator sites or the informed consent documents provided to the patient specify that the clinical service will be provided free to all enrollees."

❖ The proposed CRP appropriately does not require that the research study be specifically designed to assist Medicare beneficiaries or enroll a certain proportion of Medicare beneficiaries.

❖ The proposed CRP clarifies that the Medicare-specific standards would permit coverage if the study is not designed "exclusively" to test toxicity or disease

[5] 21 C.F.R. § 312.2(b)(1)

pathophysiology. This revises the 2000 NCD, which required that therapeutic intent be the primary objective of the clinical trial. Thus, the proposed CRP appears to cover certain Phase 1 studies. It also appears to extend coverage for observational clinical studies that some feared were not covered under the NCD 2000.

❖ As stated above, the proposed CRP requires the clinical trial to be registered to qualify on clinicaltrials.gov and requires that the investigators and/or sponsors periodically make the data publicly available. It is not certain how this data availability provision will work. For example, in certain cases, it is important to withhold results to avoid creating the Hawthorne Effect—namely, where information affects the experiences of the enrolled subjects. In addition, it is not clear how this periodic reporting obligation will work with mandated securities filings or with industry needs to protect intellectual property.

Although the proposed CRP may undergo further refinement, it is likely that the final rule will maintain several important features that influence how institutions craft clinical trial billing policies and procedures.

❖ The proposed CRP declines to comment on the impact of the Medicare Secondary Payor (MSP) Rule on claims relating to subject injury or claims not covered by insurance. Research sponsors, IRBs, investigators, and sites understandably want to minimize the financial burden on subjects associated with medical injuries out of a sense of fairness and concern that individuals may be reluctant to participate if they would face unexpected medical bills. It is reasonable for sponsors to volunteer to be the back-up quarterback, picking up the ball only if the primary coverage—Medicare or other third-party payers—deny claims. Because the proposed rule does not squarely address whether and how an industry sponsor may cover either denied claims or costs of subject injuries, and because the MSP Rule has been interpreted by some to mean that Medicare will not pay for claims if another liability insurer—in this case, the sponsor—is in the wings and willing to pay, sponsors may feel that they must effectively agree to pay for all or none of the classes of claims and expenses. All interested will benefit if the final rule provides more clarity.

❖ The proposed NCD states that one pathway for being deemed an approved study is to be reviewed and funded by specific federal agencies. It is not clear what type of "review" is necessary.

Conclusion

As under the 2000 NCD, institutions providing items and services during the course of a clinical trial need to be mindful not to submit claims for Medicare reimbursement that do not meet the coverage standards that CMS has announced. Institutions that improperly submit claims to the Medicare program face repayment obligations and potential false claims act repercussions. Industry entities, too, need to be mindful of reimbursement rules so that these sponsors can draft clinical research budgets that do not leave research sites in a financial hole.

Although the proposed CRP may undergo further refinement, it is likely that the final rule will maintain several important features that influence how institutions craft clinical trial billing policies and procedures. *G2 Compliance Report* will publish a second article following the issuance of the final rule describing its provisions and including implementation suggestions.

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Lab Network Policy, *from page 1*

only when physicians make continued, material use of nonparticipating laboratories, and then only after an opportunity to dialogue with those physicians and understand the reasons why nonpar laboratories are being used."

United also "will not attempt to hold physicians accountable when their patients independently choose to use their out-of-network benefit by seeking services from an out-of-network laboratory provider." In addition, CAP says that United clarified in a separate communication that if a hospital is in the United network, then the hospital's laboratory is also considered to be an in-network laboratory provider and exempt from this policy.

United told CAP that it would work with participating physicians if there are gaps in the network and will add additional laboratory providers when appropriate. Laboratories should work with their local referring physicians to become participating providers in the United network, the company advises.

Medicare Officials Urge Early Adoption Of NPIs

Healthcare providers should not wait to apply for and begin testing their National Provider Identifier (NPI) or to develop a contingency plan if they were not able to meet the May 23, 2007, deadline for compliance, warn officials with the Centers for Medicare and Medicaid Services (CMS), who spoke May 10 during a national roundtable on NPI implementation.

"Noncompliant entities should be developing their contingency plans now and testing should be starting imminently, if it hasn't already," advised Lorraine Doo, senior policy advisor in the office of E-Health. "CMS reserves the right to investigate complaints that come in after May 23, 2007, and retains the right for enforcement actions and for invoking civil money penalties."

CMS is not advising providers on what a contingency plan should contain "because each case is going to be evaluated individually based on the case at hand."

While CMS recently announced a contingency plan for those providers unable to meet the May 23, 2007, deadline for NPI compliance, Medicare fee for service (FFS) could actually begin requiring NPI use as early as July 1, 2007, by primary providers if CMS judged that a sufficient number of claims contained these NPIs. Providers will receive advance notice of any such decision, according to Transmittal 1225 (change request 5595), issued April 20, 2007.

The transmittal, which details the Medicare fee for service implementation contingency plan, notes that as soon as the number of claims submitted with an NPI for primary providers is sufficient to do so, Medicare FFS will begin rejecting claims without an NPI for primary providers. Medicare FFS will evaluate claims submitted in May 2007, and if the analysis shows a sufficient number of submitted claims contain an NPI, Medicare will begin to reject claims on July 1, 2007, that do not contain NPIs.

If a sufficient number of claims do not contain NPIs in the May analysis, Medicare FFS will assess compliance in June and determine whether to begin rejecting claims in August 2007.

Primary providers are defined as billing, pay-to, and rendering providers. All other providers are defined as secondary—they include "referring, ordering, supervising, facility, care plan oversight,

purchase service, attending, operating, and 'other' providers," says CMS.

Legacy numbers are acceptable for second providers until May 23, 2008. If the NPI is present for secondary providers, the NPI must only be edited to determine that it has 10 digits; begins with a 1, 2, 3, or 4; and that the 10th position of the number is a correct check digit.

CMS is not advising providers on what a contingency plan should contain "because each case is going to be evaluated individually based on the case at hand," notes Doo. "However, if we do receive complaints, there are a number of things we may ask for, such as the date you received your NPI and the date you actually shared your NPI with health plans and clearinghouses." CMS will also look at the schedule you have for testing your NPI, she added.

Paper Claims

Marlene Biggs, NPI Medicare FFS lead, Office of Information Services, advised during the audio conference that Medicare will begin rejecting the old, Part A, paper form UB-92 after May 22, 2007, and will only accept the UB-04. The date for Medicare to continue accepting the old CMS-1500 (12-90) form has been extended from April 1, 2007, to July 1, 2007. Medicare will begin rejecting the CMS-1500 (12-90) after July 1.

Both the new UB-04 and the CMS-1500 (08-05) allow reporting of NPI and legacy provider numbers together. For NPI purposes, Medicare will treat paper claims, direct-data entry claims, and claims submitted using CMS's free billing software the same as electronic claims.

"Whatever date Medicare begins rejecting electronic claims that do not contain an NPI in the primary provider field, we will also reject paper, DDE, and free billing software claims without an NPI at the primary level," said Biggs.

Medicare officials also noted that the data dissemination notice to facilitate NPI sharing via a centralized database has yet to be finalized. It is still under review at the Office of Management and Budget, they said. The notice will specify what data are available from the National Plan and Provider Enumeration System (NPPES) and how to access the data, plus offer help with NPI crosswalks.

The lab industry has pointed to this delay as a major factor impeding NPI readiness. Without access to the NPPES database, payers and providers must contact each trading partner to obtain NPI data, a time-consuming and costly process, noted Kimberly Williams, LabCorp associate vice president, during an April 30 audio conference sponsored by Washington G2 Reports.

Resources

- Transmittal 1225: www.cms.hhs.gov/Transmittals/
- Transcript of May 10 CMS roundtable: www.cms.hhs.gov/NationalProvIdentStand/. Click on "NPI Contingency Planning."
- NPI Countdown to Compliance: Are You Ready? Recordings from Washington G-2 Reports audio conference may be purchased for $219 ($199 for G-2 Subscribers). To order, go to *www.g2reports.com* and click on "Recordings."

Additional Information

- CMS NPI Web site: www.cms.hhs.gov/NationalProvIdentStand/
- To apply for an NPI: https://nppes.cms.hhs.gov
- Guidance on compliance with HIPAA NPI rule: www.cms.hhs.gov/NationalProvIdentStand/Downloads/NPI_Contingency.pdf
- Guidance on disclosure of NPIs by healthcare industry entities: www.cms.hhs.gov/NationalProvIdentStand/Downloads/NPIdisclosure/pdf

News-At-A-Glance

Operation Strike Force: Federal officials in May arrested 38 people in the first phase of a targeted criminal, civil, and administrative effort against individuals and healthcare companies that fraudulently bill the Medicare program. The arrests in the Southern District of Florida are the result of the establishment of a multi-agency team of federal, state, and local investigators designed specifically to combat Medicare fraud through the use of real-time analysis of Medicare billing data.

OIG Enforcement Priority: Quality of care remains a key enforcement priority for the Department of Health and Human Services Office of Inspector General, IG Daniel Levinson said April 24 during a presentation to the Health Care Compliance Association's 2007 Compliance Institute. While the OIG has previously targeted long-term care settings, the agency's focus had broadened to include other settings. Levinson said that future work for the OIG includes compliance program guidance for nursing homes, as well as resource guidance for board of directors on their responsibilities for overseeing quality of care.

Plasma Sales: An increasing proportion of the sales of intravenous immune globulin (IVIG) is taking place at levels below what Medicare pays providers for the blood-based product, according to a new Department of Health and Human Services Office of Inspector General (OIG) report. The report found that, in the third quarter of 2006, 56% of IVIG sales to hospitals and 59% to physicians by the three largest distributors occurred at prices below the Medicare amount. The report, "Intravenous Immune Globulin: Medicare Payment and Availability," is available at *www.oig.hhs.gov*.

IRS Memo: In a memorandum issued May 11, 2007, the IRS issued long-awaited guidance on exempt hospitals sponsoring subsidized electronic health record (EHR) programs. Last August, the Department of Health and Human Services published regulations permitting hospitals (and others) to provide, within defined parameters, EHR software and technical support to staff physicians at subsidized prices without violating the Stark law or anti-kickback statute. Since then, industry groups have been seeking similar comfort from the IRS. This memo finally provides that comfort. The memo is available at *www.irs.gov/pub/irs-tege/ehrdirective.pdf*.

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