The Centers for Medicare and Medicaid Services (CMS) has initiated a new, national Medicaid fraud provider audit program, called the Medicaid Integrity Program (MIP). Through the MIP, CMS contracts with a number of Medicaid Integrity Contractors (MICs) to assist states to better combat provider fraud, waste and abuse. MIP audits have begun operation in California, resulting in the examination of Medicaid payments to providers, with the objective of identifying potential overpayments.

The MIP consists of contractors for three purposes: the review of providers (Review MICs), audits (Audit MICs) and education (Education MICs).

Review MICs:

The Review MICs analyze Medicaid claims data to identify high risk areas and potential vulnerabilities, provide leads to Audit MICs, and use a data-driven approach to ensure focused efforts on providers with aberrant billing practices. The Review MICs review data submitted, originally for research purposes, by the states to CMS to identify suspected overpayments. Because some of this data was not submitted with reviews in mind, CMS is attempting to get more complete data from states. The state agencies may also identify providers to be audited.

The Review MICs first review this data for rules-based overpayments, such as whether a service is allowable or whether a service was separately billed when it should have been part of a bundled service. Based on hundreds of queries or algorithms that Review MICs run against the data, Review MICs identify outlier providers whose practices appear sufficiently egregious to justify a recovery effort or a more careful examination. At this time, CMS has not identified a Review MIC for Region IX (encompassing California, Arizona, Nevada, Hawaii and the Pacific Islands), but is performing this function itself at least for the State of California.

The Review MICs do not have restrictions on how far they can “look back” to identify overpayments. However, CMS has indicated that in most cases, Review MICs should only “look back” as far as would be permitted pursuant to state law and policies. In California, case law suggests that the Department of Health Care Services is bound by the doctrine of laches to a “look back” period of three or four years, unless the Department of Health Care Services can demonstrate why a longer delay is excusable and that the delay did not prejudice the provider.

On a monthly basis, the Review MICs identify potential auditees to CMS. After conferring with the states in an attempt to avoid duplication of fraud efforts by the states, CMS sends the list of potential auditees to the Audit MICs.
Audit MICs:

The Audit MICs initiate audits by sending a "notification letter" to providers, requesting records from the provider. In general, the Audit MICs should give at least two weeks notice before the commencement of any audits, but the time allowed for record production has ranged from ten to forty-five days. Unlike the Medicare Recovery Audit Contractors, the Audit MICs are not subject to any limitations as to the number of medical records a MIC can request in a month.

The Audit MICs may conduct either field or desk audits. On-site audits will often commence with an entrance conference. The Audit MICs have the authority to request records, interview providers and their office staff and enter providers’ facilities. The Audit MICs must perform audits according to the General Accepted Government Auditing Standards (GAGAS).

After the completion of the audit, the Audit MIC will prepare a draft audit report with preliminary audit findings and tentative conclusions. The Audit MIC will share the draft report first with CMS and then with the state Medicaid agency for review and comment, specifically to ensure that the state’s Medicaid policies were appropriately interpreted by the MIC. Afterwards, the Audit MIC will share the draft report with the provider, generally giving the provider 30 calendar days to comment on any findings or conclusions or provide additional information. Based on the provider’s input, the Audit MIC will send a revised draft audit report to CMS for review. CMS will share the revised draft audit report with the state Medicaid agency for further review and comment.

CMS will then issue a final report to the state. The state will notify the provider of the final audit findings and will utilize existing state administrative procedures to recover any overpayments.

Audit MICs are also expected to make referrals to the Office of the Inspector General if fraudulent behavior is detected.

The MIP has begun conducting approximately 500 audits in approximately nineteen states and the District of Columbia. The nineteen states are: Alabama, Arkansas, California, Colorado, Delaware, Florida, Georgia, Idaho, Kentucky, Louisiana, Maryland, New Mexico, Nevada, North Carolina, Oklahoma, Pennsylvania, South Carolina, Texas, and Virginia. CMS anticipates that by the end of this calendar year, audit MICs will have initiated audits in all CMS regions. Approximately 44% of the current audits are being conducted on hospitals, 29% on long-term-care facilities, 21% on pharmacies and the rest on other providers. The Audit MIC for Region IX is Health Management Systems.

At this time, identified audit process issues include: requests for information outside the scope of the audit, short timeframes to produce documents, looking back up to five years (beyond the scope of state law), some audits are duplicative to other audits and mis-interpretation of state law.

When providers are notified of an audit, we advise that providers prepare to establish an internal, interdisciplinary MIC team that includes legal, finance, clinical, compliance and information technology personnel. Providers should identify one MIC point of contact for internal and external MIC communications. We further recommend that providers develop a central tracking mechanisms for all incoming and outgoing communications with the MICs and coordinate the tracking mechanism with a communications structure, including record reviews and appeal of recoupment deadlines. We are happy to provide further guidance and assistance on responding to a MIP audit.

Education MICs:

CMS has identified the Education MIC to perform a gap analysis of existing education and training efforts to Strategic Health Solutions. Strategic Health Solutions will identify potential areas for additional education and training areas. CMS expects to award an additional Education MIC contract for a web-based curriculum sometime in the near future.

For more information about the MIP, or how to respond to any requests from a MIC, please contact John Hollow, Byron Gross or Jodi Berlin in Los Angeles at 310.551.8111; Mark Reagan, Felicia Sze or Paul Deeringer in San Francisco at 415.875.8500, or Mark Johnson in San Diego at 619.744.7301.
Untangling the FTC Breach Notification Rule

By Michael A. Dubin


Originally proposed in April 2009, the FTC Breach Notification Rule (FTC Rule) requires compliance by vendors of personal health records (PHR) — such as web-based repositories used for tracking individual health information — and entities offering third-party applications for PHRs, such as information uploaded from heart monitoring equipment. It does not apply to HIPAA-covered entities or business associates; they are covered under the HHS companion regulations. The FTC rule also explicitly excludes physicians from the coverage of the FTC Rule. The effective date of the FTC Rule is September 24, 2009.

For PHR vendors, the FTC Rule requires notification of U.S. citizens and residents and the FTC when a breach in security occurs which involves the unauthorized acquisition of unsecured identifiable health information. Like the HHS regulations, discovery occurs when the breach is known or should reasonably have been known by the vendor.

For third party service providers, notification must be made as specified in the contract between the third party service provider and the PHR vendor or, in the absence of such a contract, to a senior official at the PHR vendor with an acknowledgement that such a notification was received. In turn, the PHR vendor must provide a breach notice to its customers. The third party service provider must additionally include an identification of each individual whose information was acquired during such a breach.

Under the FTC Rule, notification must be made “without unreasonable delay,” but in no case more than 60 calendar days after discovery. The notification period may actually begin before an entity conclusively establishes that a breach has occurred. The FTC clarified that the 60-day clock starts early and will not be delayed so that an entity can fully complete its “investigation to determine whether unauthorized acquisition has occurred, whether PHR identifiable health information has been breached, or whether the information breached was unsecured.”
For breaches involving 500 or more people, the local media must be notified within the 60-day period. Of course, the FTC must always be notified of a breach. Beaches involving 500 or more people must be reported to the FTC within 10 business days of discovery (the 60-day period still remains in effect for the public notification). For smaller sized breaches the PHR vendor or related entity may report to the FTC annually, by maintaining a log and submitting it to the FTC within 60 calendar days of the end of the year, together with a copy of the notifications sent to consumers.

The notice must be in plain language and include the following:

- What happened (including the date of the breach and the date of discovery);
- A description of the types of information involved (such as the full name, SSN or date of birth);
- The steps individuals should take to protect themselves;
- A brief description of what the entity is doing to investigate the breach, to mitigate harm and to protect against further breaches; and
- The contact procedures and information for people to follow up with questions.

E-mail notice is sufficient if the individual is given a clear, conspicuous and reasonable opportunity to receive notice by first-class mail and does not exercise that choice. If there are 10 or more individuals for whom the PHR vendor or related entity does not have current contact information, it must provide substitute notice either by posting notice for 90 days on the home page of its Web site, or by publishing the notice in major print or broadcast media. Any media or Web posting must include a toll-free phone number, which is to remain active for at least 90 days, for individuals to call to learn more information.

To ensure that consumers only receive a single breach notice for a single breach, the FTC clarified that the notice should come from the entity with whom the consumer has a direct relationship. If a PHR vendor is both a business associate and deals directly with consumers, it need not notify the customer receiving a breach notification on behalf of a HIPAA-covered entity.

Although the final FTC Rule largely follows the original, proposed rule, there are some notable differences in the two, which include:

- The FTC Rule expressly adopts the HIPAA preemption analysis. Federal law preempts any “contrary” state law, but an additional state requirement that is not contrary is not preempted. PHR vendors and third party service providers should follow federal law, as well as any state regulations that have even more stringent requirements.
- The rule requires PHR vendors and related entities to notify their third-party service providers that the service providers are subject to the rule.
- The Rule contains a “Notice of Breach of Health Information” form (which can be found at http://www.ftc.gov/healthbreach), and should be used by vendors and related entities beginning on the effective date of the rule, September 24, 2009.
- There is no prescribed content for notices to the media, eliminating the original FTC Rule's requirement to include the same information required for individual notifications.

Stark Deadline for Restructuring Certain Deals and Leases Arrives

Many providers remain unprepared for the sweeping Stark changes effective October 1, 2009. If you are involved in any “under arrangements” ventures or “per-click” or “percentage” leases, then the new regulations may require that your venture or lease have been restructured by October 1, 2009 to comply with the law. This short FAQ may be helpful in assessing your situation:

**Question:** What is an “under arrangements” venture?

It’s an arrangement in which a hospital bills Medicare for a hospital service that is performed by an outside entity, or third party, pursuant to an agreement with the hospital (e.g., a hospital contracts to purchase MRI services for its inpatients from a medical group that owns an MRI across the street from the hospital). Generally, “under arrangements” ventures where referring physicians own (directly or indirectly) the third party providing the services, may need to restructure by October 1, 2009 to comply with Stark.

**Question:** Why would a physician-owned entity, providing services “under arrangements,” no longer comply with Stark on October 1, 2009?

On October 1, 2009, the definition of an “entity,” to which physician owners are prohibited from referring expanded to include not only the entity billing Medicare for Stark-designated health services (DHS), which include all Medicare-covered inpatient and outpatient hospital services, but also any entity “performing” a service billable as DHS. In the typical “under arrangements” relationship the contracting entity would likely be considered to be performing the service it provides to the hospital, which is then billed by the hospital as an inpatient or outpatient service - hence it is a DHS.

**Question:** What types of leases are prohibited effective October 1, 2009?

Space and equipment leases no longer satisfy the applicable lease exceptions in Stark if they provide for “per unit of service” or per click rent, meaning rent calculated based on the “units of services” provided, in the space or using the equipment, if any of those services are provided to patients referred by a physician lessor, or rent calculated based on a percentage of revenue, charges, collections generated or otherwise attributable to services performed or business generated in the space or using the equipment.

**Question:** How do I know if I need to restructure, and if I must, how best to do so?

You should consult with a Stark legal expert immediately. We helped dozens of hospital and physician clients determine if their transactions need to be restructured, and if so, how best to restructure them to meet the October 1, 2009 deadline.

**Question:** What should I do if I missed the October 1, 2009 deadline?

First, you need to stop any non-compliant arrangement as soon as possible. How you do that will depend on the specifics of the arrangement. In some cases, you might be able to terminate a lease or agreement immediately or on short notice. In other cases, you may need to arrange an alternative provider. In some cases you will need to cancel scheduled procedures, or hold Medicare claims. Once you have stopped the non-compliant arrangement, you will need to assess whether you have a period of non-compliance starting October 1, 2009 and ending on the date the arrangement stops, and if so, how to remediate that period. Addressing a period of prior non-compliance with Stark is a delicate and complex undertaking, which potentially can involve Medicare repayments or self-disclosure, and is generally best handled with assistance from experienced counsel.

For additional information, please contact Charles Oppenheim in Los Angeles at 310.551.8111 or Steve Phillips in San Francisco at 415.875.8500.
C A L E N D A R

Oct.  1  L.A. County Bar Assn. 6th Annual Healthcare Law
Compliance Symposium, Los Angeles.
Charles Oppenheim co-presents Stark Law Update for Hospital and Physician Arrangements.

5  NASL Annual Meeting, Chicago.
Mark Reagan presents Update on CMS Recovery Audit Contractor (RAC) Program.

6  AHCA Annual Fraud & Compliance Forum, Baltimore.
Patric Hooper presents Hot Topics in Federal False Claims Act Cases.

6  AHCA National Convention, Palm Springs, CA.

15  AHHA Life Sciences Institute, Washington, D.C.
Stephen Phillips speaks on HITECH and HIPAA.

22  Health Financial Systems User Meeting 2009, Las Vegas
Mark Hardiman presents Fraud & Abuse Update and Jon Neustadter presents Recent Medicare Cases.

Nov.  6  CCLA Annual Meeting, Newport Beach, CA.
Patric Hooper speaks on Current Laboratory Issues.

Nov. 11  CAHF Annual Convention, Palm Springs, CA
Mark Reagan presents The Changing Landscape of Transfer/Discharge Hearings – From DPH to DHCS.

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