WASHINGTON G–2 REPORTS

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

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Vol. 28, No. 15, May 21, 2007

CAP Revs Up Its Drive To Overhaul CLIA Cytology PT

"Despite genuine efforts … to work with CMS, the regulatory process clearly is broken … We need to take our case to Congress now"—Thomas M. Sodeman, MD, president of the College of American Pathologists.

Faulting the government for repeated delays in delivering on its promise to propose revised rules for CLIA cytology proficiency testing, the College of American Pathologists says it's time to go all-out for a legislative solution.

In a May 10 letter to members, CAP president Thomas M. Sodeman, MD, said: "The Centers for Medicare & Medicaid Services has again shifted its timetable for [the proposal] until December 2007. [This] means pathologists and cytotechnologists will continue to be tested under an outdated and ineffective program through 2008, and worse still, likely 2009."

Good-faith efforts to work with CMS on the proposal have come to naught, Sodeman said. "It's pretty clear that the regulatory process has failed the profession, and we now need to take our case to Congress. After all, it is only because of congressional pressure that [CMS] agreed to revisit the rules in the first place."

He urged members to lobby their representatives in support of House legislation (H.R. 1237) that embodies a CAP-endorsed replacement for the current gynecologic cytology PT program under CLIA (the Clinical Laboratory Improvement Amendments). *Continued on p. 2*

INSIDE *NIR*

Physician Groups Grapple With Medicare Fee Fix

The American Medical Association and other physician groups are working on a legislative proposal that would block the 10% cut in Medicare physician fees projected for 2008 as well as cuts of 5% annually over the following nine years.

A draft proposal urges Congress to either immediately repeal the Sustainable Growth Rate (SGR) system for annual updates to the Part B physician fee schedule or approve short-term fee hikes until a new payment system is in place by 2016. In lieu of SGR repeal, fee increases would be guaranteed for a minimum of two years. The Medicare Payment Advisory Commission recommends a fee update of 1.7% in 2008, with subsequent updates through 2015 based on the rate of increase in the cost of providing services.

For 2007, Congress blocked a 5% cut, froze fees at 2005 levels, and created a new bonus payment of 1.5% for doctors who report specified quality measures. Democratic health leaders say they will address the SGR problem, but the big question is how to pay for it (*related story, p. 3*).

For 2007, cytology PT testing continues under the current CLIA program. CAP and ASCP are the two nationally approved PT providers. The Maryland health department runs an approved program for specimens of state residents.

CLIA Cytology PT, *from p. 1*

Rulemaking Delays

Sodeman's letter came on the heels of release of the HHS semiannual regulatory agenda in the April 30 *Federal Register*, which indicated that the revised rules had not moved beyond the proposal stage. Since early 2006, CAP notes, CMS has assured Congress and the profession that it is moving "expeditiously" on the rulemaking, but keeps putting off a "date certain." Initially, the agency said a proposal would be out in February 2007, then July, then "sometime this year," and now December 2007, CAP points out.

CMS agreed to revisit the cytology PT rules after the House in December 2005 passed a bill to suspend the current program until certain changes backed by CAP were considered. While the revisions are in the works, CMS said it would use PT to emphasize improvements vs. punitive sanctions, as long as all affected sites and personnel participated in a CMS-approved cytology testing program (*NIR, 27, 8/Feb 6 '06, pp. 4-5*).

Asked by the *National Intelligence Report* to comment on the latest rulemaking delay, a CLIA official said: "We are hoping to have the Notice of Proposed Rulemaking out this year. The delay in publishing is basically due to limited resources and significant workload. We are doing our best to move this along. The 17 recommendations are more complex to articulate in regulatory language, and there is a lot of history to be encompassed in the Preamble. Remember that a reg is not just standards, but needs a detailed preamble, impact statement, and paperwork burden [assessment] as well."

CAP's Legislative Strategy

The College argues that the existing cytology PT program—which operates under rules written in 1992 but not enforced nationally until 2005—does not reflect current cytology science and clinical practice. CAP is building support for an alternative—H.R. 1237, which would replace annual individual PT for pathologists and lab professionals who perform Pap smear work with annual continuing medical education to improve screening and interpretation skills (*NIR, 28, 10/Mar 12 '07, p. 2*).

John Scott, CAP's vice president for advocacy, told *NIR* a Senate companion bill is in the works, and he is optimistic that the legislation could pass as a stand-alone bill (as happened in the House in 2005) or as part of a broader healthcare package. "There's a reservoir of support [for it], " he said, "and it is not a partisan issue." H.R. 1237 now has 36 co-sponsors and is supported by 60 national pathology and lab groups and state pathology societies. And the American Medical Association has recently joined in backing the bill, Scott noted.

Randy Eckert, MD, who chairs CAP's Council on Government and Professional Affairs, told *NIR*, "We don't believe the current program's individual PT testing will result in the improvements that CMS expects." It doesn't reflect the interdisciplinary team approach that characterizes cytology work today, he said.

While CLIA officials say they are "locked into" the current program by the wording of the CLIA statute, Eckert countered that, if so, they could seek a legislative fix, but have "vehemently opposed this, to the point of telling [the] workgroup [recommending revisions] that it would not be allowed to consider any statutory changes." CAP and others, he said, "have tried very hard in good faith to correct serious flaws—it has been difficult at best—and seeing repeated delays does indicate that the only way to fix this is through legislation."

Finding The Money To Prevent Medicare Physician Fee Cuts

Health leaders in the Democratic-controlled Congress have promised to prevent the scheduled 10% cut in Medicare physician fees in 2008 and address reform of the Sustainable Growth Rate (SGR) system for calculating annual updates. But how to pay for it is the question. Under congressional pay-as-you-go rules, new spending must be offset by cuts elsewhere.

A physician fee fix is a priority in fiscal 2008 budget blueprints passed by the House and the Senate (*NIR, 28, 12/Apr 9 '07, p. 3*). But even a zero update in 2008 would be expensive—$10 billion by some estimates—while an SGR overhaul would cost $218 billion over 10 years, the Congressional Budget Office says.

Medicare managed care has long been ripe for cuts, thinks House Ways & Means health subcommittee chairman Pete Stark (D-CA), but other healthcare providers could be tapped as well, he warned recently, telling the hospital industry not to assume a 100% update next year. "No program or payment system, no matter how big or small, is above review. Everything is on the table in terms of refinement and other adjustments," he reiterated at a May 15 hearing.

Stark has long said Medicare Advantage (MA) plans are overpaid, compared to traditional fee-for-service (FFS). Currently, average MA payments will rise by 3.5% in 2008, CMS estimates. MA plans get 12% more than FFS providers, the Medicare Payment Advisory Commission and the Congressional Budget Office have said, a figure hotly contested by the managed care industry, which argues it does not account for beneficiary gains in added benefits and little or no premiums or copays. Equalizing payment between MA and FFS plans would cut Medicare spending by about $65 billion over five years, the CBO says.

Cuts in the MA program, enacted by the previous GOP-controlled Congress, would be controversial, given the rapid rise in enrollment rates and local coverage. It now serves one in five beneficiaries, up from one in 10 four years ago, said CBO director Peter Orszag, predicting that 26% of beneficiaries will be enrolled in MA by 2016. Republicans defend the higher MA rates, saying plan enrollees get catastrophic coverage and added benefits and that MA plans have improved access to healthcare in small urban and rural markets.

Boom Time For Medicare Advantage

Total Medicare beneficiaries: 43 million.

Number in Medicare Advantage: 8.3 million (19%) vs. 81% in traditional fee-for-service.

Rapid enrollment growth: Number of enrollees increased from 5.3 million (across 285 contracts) in 2003 to 8.3 million (across 604 contracts) as of February 2007. Growth largely attributed to higher plan payments and new marketing opportunities under the Part D drug benefit.

Fastest growing MA sector: Private FFS plans, going from 209,000 enrollees in December 2005 to 1.3 million in 2007, an increase of over 500%.

Access: Virtually all beneficiaries have access to a private plan, mainly due to the emergence of private FFS plans and regional PPOs in rural areas. Enrollment rates vary widely across states. Nearly half of all MA enrollees in 2006 lived in five states: Arizona, California, Florida, New York, and Pennsylvania. Less than 1% were enrolled in four states: Alaska, Maine, New Hampshire, and Vermont.

Sources: Congressional Budget Office, Henry J. Kaiser Family Foundation.

focus on: NPI Compliance Policy

Q&As On NPI Contingency Plan For Medicare Fee-For-Service

When Medicare unveiled its contingency plan for fee-for-service (FFS) providers that cannot meet the May 23, 2007 deadline to comply with National Provider Identifier (NPI) requirements, it triggered a lot of questions on the practical side, including plans to "fast track" required NPI use by certain providers.

The NPI is one of a series of identifiers required by HIPAA (the Health Insurance Portability & Accountability Act of 1996) to facilitate electronic healthcare data exchange. The NPI is a unique 10-digit numeric identifier that neither expires nor changes. It replaces all legacy provider identifiers now in use, such as UPINs, OSCARs, individual plan identifiers, etc. CMS began issuing NPIs on May 23, 2005, and affected entities had until May 23, 2007, to complete NPI implementation (small health plans had an additional year).

To answer some of the questions raised by the new NPI contingency plan for FFS providers that cannot meet the above deadline, the Centers for Medicare & Medicaid Services held a May 10 national roundtable, where a panel of agency officials discussed the plan in detail and fielded calls from the public. Summarized below are some of the key issues tackled.

NPI Compliance At A Glance

❑ ***General Contingency Policy***

Applies to healthcare providers and other entities covered under HIPAA (the Health Insurance Portability & Accountability Act), including health plans and health information clearinghouses, that cannot meet the May 23, 2007 deadline. They have up to an additional 12 months to become compliant as long as they are making a good-faith effort to do so.

As of May 23, 2008, only NPIs will be recognized in HIPAA standard electronic transactions.

❑ ***Medicare Fee-For-Service Policy***

CMS will take a flexible approach in enforcing FFS policy regarding NPI compliance, saying it wants to minimize disruptions. No penalties for non-compliance will be imposed, as long as the entity is working toward being able to accept and send NPIs.

- For some period after May 23, 2007, Medicare FFS will:
  - — Allow continued use of legacy numbers on transactions;
  - — Accept transactions with only NPIs; and
  - — Accept transactions with both legacy numbers and NPIs.
- After May 23, 2008, legacy numbers will not be permitted on any inbound or outbound transactions.

Medicare could begin requiring NPI use by primary providers on July 1, 2007 or soon after. The date depends on an assessment of claims submitted with NPIs for these providers.

When can we expect a notice on how CMS will make NPI data available, including crosswalks, to facilitate NPI exchange with trading partners?

At the outset of the national roundtable, CMS officials said they could not offer an update on this issue. The agency has said it would provide help for crosswalks between NPIs and legacy provider numbers. The notice on NPI data to be available from the National Plan/Provider Enumeration System (NPPES) is in regulatory clearance, the officials said, but it is expected to be released soon.

Government delay in issuing the NPPES notice has been a big impediment to NPI readiness, say lab groups and other providers. Access to a centralized database is essential, they say, to obtain NPIs and arrange for a smooth exchange of NPIs with trading partners. Currently, getting NPIs is time-consuming and costly, note industry groups. Providers must collect them by going from one trading partner to another.

How will CMS handle the phase-out of the UPIN registry during the transition to sole NPI use?
Also at the outset of the call, officials said they could give no update on this topic, except to note that guidance on the UPIN registry is expected shortly, "perhaps within the next week or so."

What should a contingency plan look like?
There is no checklist per se, said Larraine Doo, senior policy advisor in the CMS office of e-health, during the roundtable call. It is up to each provider to devise a plan that fits its situation and that of its trading partners.

If a complaint is received, she said, CMS would look at when you got NPIs, when you shared them with your trading partners, and what schedule you have set to test NPI software and data exchanges with your trading partners.

With regard to health information clearinghouses, CMS would look at dates set for testing, the flow of communications with clients regarding testing, and the time frame for completing crosswalks from legacy identifiers to NPIs.

When complaints involve vendors, CMS has no authority to intervene; however, if such a complaint is lodged, the agency could help in gaining cooperation from the vendor.

When should a group practice start using NPIs?
Right away. While the group handles HIPAA transactions and the employed physicians don't, the group, as an employer, could require the doctors to obtain NPIs and use them to identify themselves as the rendering physician on the claims the group submits. Also, health plans can require enrolled physicians to obtain NPIs in order to participate. Medicare is one such health plan.

Part B contractors are no longer accepting group practice claims that report the individual rendering PIN or individual rendering NPI in either the billing or pay-to provider ID fields. The group should either enter its group NPI *or* its group NPI and legacy PIN number pair in either of these fields.

When will Medicare begin rejecting claims without an NPI in the primary billing provider field, and what is meant by a primary provider?
Primary providers are billing, pay-to, and rendering providers. When CMS judges that a sufficient number of claims contain the NPIs of these providers, it may start rejecting claims that do not contain these NPIs. That could be July 1 or soon after.

All other providers are defined as secondary. They include referring, ordering, supervising, facility, care plan oversight, purchase service, attending, operating, and "other" providers. Legacy numbers are acceptable for these providers until May 23, 2008.

If a secondary provider's NPI is on a claim, it will only be edited to assure that it has 10 digits, that it begins with "1", "2", "3", or "4", and that the 10th position of the number is a correct check digit.

What is a "sufficient number" that would trigger required NPI use for primary providers?
At this time, there is no clear, defined number, CMS officials said. There is no specific statistic or number of claims in mind, they noted, adding that the determination of "sufficient number" will be based on other factors as well.

When will paper claims start being rejected?
Medicare will begin rejecting the old Part A paper form, the UB-92, after May 22, 2007, and will only accept the new UB-04.

Medicare will continue accepting the old CMS-1500 (12-90) form until July 1, 2007. Its use had been set for April 1, but was delayed when CMS discovered printing errors on the new form. Medicare will begin rejecting the CMS-1500 (12-90) as of July 1.

Both the new UB-04 and the new 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 sets to start rejecting electronic claims that do not contain an NPI in the primary provider field will also be the date when Medicare starts rejecting paper, direct data entry, and free billing software claims without an NPI at the primary level," Marlene Biggs, NPI Medicare FFS lead in the CMS office of information services, told the roundtable audience.

More On The National Provider Identifier

- Medicare FFS contingency plan for NPI implementation (CMS Change Request 5595, April 24, 2007): *www.cms.hhs.gov/transmittals*.
- To apply for an NPI, go to the National Plan/Provider Enumeration System (NPPES) Web site at *https://nppes.cms.hhs.gov*.
- For updates on NPI policy, go to *www.cms.hhs.gov/NationalProvidentStand*.
- The NPI project enumerator is Fox Systems, Inc. (Scottsdale, AZ), under contract with CMS. There are limits to what the contractor can respond to, notes CMS. It can answer questions about the status of an NPI application, a lost number, trouble accessing NPPES, a forgotten password, and clarification on information needed on an NPI application. The toll-free number is 800-465-3203. For other issues, CMS urges providers to check the NPI Web site listed above.

What identifier should be used for referring/ordering providers from Canada or elsewhere outside the U.S.?
You may continue using their legacy numbers until May 23, 2008; as of then, however, they must have an NPI. Obtaining an NPI is not limited to providers practicing in the U.S., so encourage your referring/ordering providers outside the U.S. to apply for an NPI as soon as possible.

What should a provider do when it has the required NPIs, but the software for NPI exchange is not ready? Should you wait until you get all the software tested?
You should start testing with a small number and make certain it works on your end in particular, said CMS officials. Then you can move to a larger claims volume as more of the software becomes available.

Our hospice has made every effort to get NPIs from attending physicians, but we are having trouble doing so. What should we do now?
Continue your effort, and start using the NPIs you already have. But remember, the attending physicians would fall into the secondary provider group, so you may continue to use their legacy numbers until the 2008 end date, said CMS officials.

When a provider confronts an entity whose NPI contingency plan differs from the Medicare FFS guidance and files a complaint, what will CMS do?
CMS would look at the particulars of the case, such as the good-faith effort made by all parties, said Larraine Doo. All HIPAA-covered entities must implement policies that conform to HIPAA requirements for accepting NPIs.

HHS Veteran Kerry Weems Nominated To Head CMS

Kerry N. Weems

Kerry N. Weems, a 24-year career veteran with the U.S. Department of Health & Human Services, is the President's pick to become the next administrator of the Centers for Medicare & Medicaid Services. The White House sent the nomination to the Senate on May 3 for confirmation.

Weems, 50, is deputy chief of staff to HHS Secretary Michael Leavitt. An expert in finance, Weems has served as advisor to several HHS Secretaries and as HHS budget director. Leavitt said in a statement that Weems' budget credentials will be "a valuable asset to CMS … He understands the large fiscal challenges facing Medicare and Medicaid and what it will take to strengthen and sustain those programs in the future. Further, he has been a leader in HHS's efforts to accelerate adoption of health information technology and better financial management systems."

One of those looming challenges comes in February 2008 when the President is required to propose, and Congress to quickly consider, Medicare spending changes to bring the program's financing below 45% of general revenues—including possible spending cuts, premium increases, or a combination of both. This is required because a "funding warning" was sounded in the latest Medicare trustees report (*NIR, 28, 14/May 7 '07, p. 6*).

If confirmed by the Senate, Weems will succeed Mark McClellan, MD, who resigned in October 2006 and has since joined two think tanks in Washington, DC—the Brookings Institution and the American Enterprise Institute. Since McClellan's departure, Leslie Norwalk has served as acting CMS administrator, but she told Leavitt early on that she did not want to be considered as a permanent successor.

Max Baucus (D-MT), chairman of the Senate Finance Committee, which will hold confirmation hearings on Weems, welcomed the nomination of a permanent successor to help improve Medicare and Medicaid, which are "essential programs for more than 80 million Americans," he noted. But given the panel's crowded calendar, hearings may not be held for several months, sources say.

Robert Kolodner Named Top Health IT Officer At HHS

Robert M. Kolodner, MD, has been formally appointed as head of the Office of the National Coordinator for Health Information Technology within the U.S. Department of Health & Human Services. He has been serving as interim head since last September, when the first national coordinator, David Brailer, stepped down. The HIT Office was established in 2004 to carry out the President's initiative to have e-health records for all Americans by 2014.

Kolodner previously was chief health informatics officer in the Veterans Health Administration within the U.S. Department of Veteran Affairs. In that position, he was chief advisor to the VA's secretary for health on IT matters and oversaw development of the VA's personal health record system for veterans.

At HHS, Kolodner will serve as principal advisor to Leavitt on all health IT initiatives and will direct implementation of the HHS strategic plan for partnering with the private sector in promoting and supporting nationwide adoption of an interoperable health IT infrastructure to facilitate e-health data exchange. A key challenge will be to tighten security and privacy protections, areas where the General Accountability Office has said more needs to be done.

♦ MEDICARE BILLING A·D·V·I·S·O·R·Y

Common Errors To Avoid On Claims To Carriers

Medicare recently released a list of common errors that providers should avoid when submitting claims. The errors most typically found on claims to Part B carriers that lead to denial, rejection, or delay because of incorrect or incomplete information include:

- ❑ The patient cannot be identified as a Medicare patient. Always use the Health Insurance Claim Number (HICN) and name as it appears on the patient's Medicare card.
- ❑ Item 32 (and the electronic claim equivalent) requires the place where the service was rendered to the patient, including the name and address—and a valid Zip code—for all services, unless rendered in the patient's home. Any claims with the word "SAME" in item 32 indicating that the information is the same as supplied in item 33 are not acceptable.
- ❑ The referring/ordering physician's name and identifier were not present on the claim. This information is required for all diagnostic services, including consultations. In addition, be aware of the new requirements for use of NPIs.
- ❑ Diagnosis codes are either invalid or truncated.
- ❑ Claims are being submitted with deleted CPT/HCPCS procedure codes.

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