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President Proposes Two-Year Medicare Physician Fee Fix

Getting lawmakers to commit to paying for more than a one-year fix may be problematic, Washington observers say, given the spending-cut climate on Capitol Hill.

In his budget request for fiscal 2012, President Obama proposes a two-year patch to cancel cuts of up to 30 percent in Medicare physician fees under the sustainable growth rate (SGR) fee update formula.

The budget, released Feb. 14, would extend the zero update on physician fees in effect since the start of this year and continue to pay at current rates. Under the proposal, the update freeze would run from Jan. 1, 2012, to Jan. 1, 2014.

The budget blueprint lays out the cost of a 10-year fix but proposes savings offsets only for the first two years. The fix would cost $18.6 billion for 2012 and $54.4 billion over 10 years. A 10-year fix would cost around $370 billion, according to the U.S. Department of Health and Human Services.

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CMS to Withdraw Controversial Physician Signature Requirement

In welcome news to the Clinical Laboratory Coalition and other providers, the Centers for Medicare and Medicaid Services (CMS) said it plans to withdraw the new Medicare policy requiring the signature of a physician or nonphysician practitioner (NPP) on lab test requisitions.

Enforcement of the policy, finalized in the 2011 physician fee schedule rule, had been set to begin April 1 following an education and outreach campaign by CMS.

The withdrawal word came in a Feb. 11 call from CMS deputy administrator Jonathan Blum to the American Clinical Laboratory Association and the American Association of Bioanalysts. An official notice of the pullback is forthcoming, he said.

CMS said it has determined the policy is unworkable and the best thing to do is to pull it back in its current form. The intention was to verify the adequacy of payments made for Part B laboratory services, but the policy does not achieve this and causes disruption and confusion. Instead, CMS said it wants to work with the laboratory community to re-evaluate the issues.

The new signature requirement was strongly opposed by a broad range of provider groups, including the Clinical Lab Coalition, the

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President Proposes Two-Year Fee Fix, *from p. 1*

While seeking a short-term fix to ever steeper SGR cuts, the administration supports a long-term reform of the SGR and urges Congress to use the two years in the proposed fix "to work on putting in place a plan to reform physician payment rates in a fiscally responsible way and to craft a reimbursement system that gives physician incentives to improve quality and efficiency, while providing predictable payments for care for Medicare beneficiaries."

Paying for the Short-Term Freeze

Obama would pay for the two-year payment freeze in physician payments through a variety of proposals, including implementing new Medicare program integrity initiatives, limiting states' ability to use provider taxes to pay the state share of Medicaid, eliminating graduate medical education payments for children's hospitals, and ensuring Medicare and Medicaid get the best prices for prescription drugs provided to beneficiaries

No cuts in benefits or increases in cost sharing to pay for the physician fee fix are proposed in the budget.

Permanent Fix Sought

While supporting a fundamental overhaul of the SGR system, the American Medical Association and the AARP welcomed the two-year fix for providing stability to beneficiaries and physicians and avoiding disruption in care as well as the administration's pledge to work for long-term reform.

The major hurdle to an overhaul is its cost—$370 billion over 10 years. Congress has had little stomach for more than short-term fixes since the SGR began triggering cuts in 2003, the shortest being last year when lawmakers approved a one-month fix. But since SGR cuts are cumulative, short-term fixes only increase the costs of a permanent solution, physician groups warn.

The President's Medicare Budget

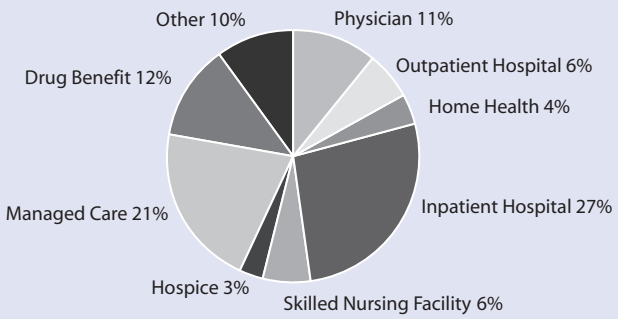
In fiscal year 2012, gross current law spending on Medicare benefits will total $548.1 billion. Medicare will provide health insurance to 50.1 million individuals who are either 65 or older, disabled, or have end-stage renal disease (ESRD), up from 48.5 million in FY 2011 and 47.3 million in FY 2010.

The above total is out of $891.6 billion in outlays by the U.S. Department of Health and Human Services. Of this amount, 54 percent is for Medicare and 30 percent for Medicaid.

Medicare Part A accounts for $203 billion in gross fee-for-service spending, Part B for $163 billion, Part C managed care for $114 billion, and the Part D drug benefit for $68 billion.

Source: HHS Budget in Brief

Medicare Benefits by Services: 2012
(current law estimates)



AAB Wins Major Victory in New York Lab Case

After 12 years of litigation, the American Association of Bioanalysts (AAB) has triumphed over the New York State Health Department in its lawsuit claiming that the department's Clinical Laboratory Evaluation Program intentionally overcharged labs to subsidize activities unrelated to regulating labs and blood banks.

On Feb. 17, the New York Court of Appeals, the highest court in the state, denied the department's appeal request against lower court judgments in AAB's favor. This exhausts the department's avenues of appeal, AAB noted in a statement, and the department now must provide refunds to the labs that were plaintiffs in the AAB suit.

This should enable the labs to recover a significant percentage of the money they paid between 1998 and 2006. The exact amount is to be determined by the court. But "all labs will benefit from the fight we have waged," noted AAB administrator Mark S. Birenbaum, Ph.D., since the department will have to conform its future billings to the lower courts' findings.

A Long and Winding Road

AAB commenced the lawsuit when it learned that expenditures were being made from lab fees for salaries of persons whose jobs had nothing to do with the regulation of New York-licensed clinical labs and in some cases who did not even work for the department. Monies were also used to pay for trips to California and Europe and cars for the New York health commissioner.

According to AAB's complaint, "Lab levies have increased sevenfold on an industry-wide basis from $2.4 million per year in 1984 to more than $17 million per year today."

After years of pretrial litigation, discovery, and appeals, the case went to trial in 2007. In 2008, retired Supreme Court Justice Edward Sheridan, who acted as a judicial hearing officer in the 30-day trial, concluded, "In effect, the [department] turned the clinical lab reference system special revenue account into an unauthorized and unsupervised revenue stream that is limited only by the bounds of the defendant's creativity."

The department appealed and on July 22, 2010, the Appellate Division, Third Department, unanimously affirmed all of Sheridan's decision. The division agreed that the fees charged to labs were "arbitrary and capricious" and that the department's "bald estimates" of the actual costs of lab regulation could not support the fees charged when the department failed to keep accurate, up-to-date financial records or even disclose those documents in support of the cost estimates.

Writing for the court, Justice Robert S. Rose noted, "The department's intention to shift as many costs as possible onto clinical labs was further revealed in testimony that the director had once boasted he had been able to transfer 17 percent of the Wadsworth Center's budget to the clinical labs" (*NIR 10, 15/August, p. 7*).

AAB's general counsel Jeffrey Sherrin, who both tried the case and successfully argued the appeal, said, "The department abused a program properly established by the legislature, used it as a slush fund, and then tried every maneuver imaginable to hide what it did."

Donating E-Health Technology to Referral Sources: N.Y. Sets Deadline for Labs to Comply With Ban

Clinical laboratories operating in New York state have until April 15 to come into compliance with the state's ban on providing electronic health record (EHR) systems and software packages to referring physicians, the state's Health Department announced this month.

The department's guidance, released in a series of frequently asked questions, gives the labs three options:

- ❏ Take back the software and discontinue prohibited services (*i.e.*, unwind contracts).
- ❏ Arrange for the one-time sale of donated software and EHR components to the referral source at fair market value and discontinue payment for the prohibited services and connectivity.
- ❏ Leave donated software of EHR components in place, continue to pay for connectivity for the components that are not lab-related, and discontinue accepting specimens for testing from the referral source.

The ban applies to pathology groups holding a clinical laboratory permit. However, pathologists on staff at a general hospital or who contract with a general hospital to provide pathology services under the hospital's permit may accept "computer services" from the hospital, including connectivity to a location off-site.

The lab must maintain documentation of the chosen corrective action and make it available to the department upon request.

Announcement of an amnesty period of 90 days (Jan. 15 to April 15) came in a series of frequently asked questions in response to the department's advisory to labs on Sept. 27, 2010, that the state's rules "do not allow cost sharing; therefore, provision of EHR, software, and training that otherwise may be permitted under federal law is prohibited in connection with a laboratory's operating in the state" (*NIR 10, 20/Nov. 4, p. 4*). Federal law allows labs to donate or cost-share up to 85 percent of the cost of EHR software but does not preempt state laws and regulations.

The department said it will not set fair market value thresholds because of the wide variety of systems and arrangements in play. "Fair market value should be determined by the lab, possibly in consultation with the manufacturer of the EHR and associated systems, and documentation should be maintained to support the value calculation."

After April 15, 2011, labs found to be in violation of the rules set forth in the Sept. 27, 2010, letter can be referred for civil or criminal penalties and administrative action against the laboratory owner. Administrative action could include denial of an application for a New York state permit.

In its warning on donations, the department said that while federal and state governments are encouraging use of health information technology, it is aware of abusive business practices—"specifically, that clinical laboratories are offering new EHRs and software packages as an inducement for practitioners to refer patient specimens for testing, resulting in a financial benefit conferred to the practitioner."

Other Frequently Asked Questions

Q. Does the ban stipulated apply to labs operating under the New York state permit that are located outside the state? Does it apply to EHR arrangements that labs in New York state enter into with clients located outside the state?

A. A lab with a New York state permit that is located outside the state is subject to the ban only for the EHR arrangements with clients in New York state. A lab in the

state is not subject to the ban for its EHR arrangements with out-of-state clients.

Q. What are the implications, including false claim risks, for labs enrolled in the state's Medicaid program whose EHR donations are compliant under federal anti-kickback safe harbors but may not satisfy the state's requirement?

A. A laboratory's operations in the state must comply with the state's rules, even if that lab participates in federal or federally supported programs (Medicare and Medicaid, respectively). Any suspect arrangements, including concern for false claims, will be referred to the state's Office of the Medicaid Inspector General, which may conduct its own investigation and impose sanctions.

Q. May a lab pay a third-party vendor for charges involved in sending reports from a laboratory information system (LIS) to the practice's EHR (a referral source)?

A. A laboratory may not pay an EHR vendor a "per click" charge for transmitting test orders or reports whenever the lab has already incurred the expense of establishing the interface that makes possible the electronic transmission of orders and reports from and to a referring practitioner.

The Health Department says it will not contact physicians to inform them of the ban and verify their compliance, but the labs may wish to share a copy of the Sept. 27 letter with their clients.

Similarly, the laboratory may not pay "per physician" usage charges (as a separate cost or a cost component of a maintenance fee) as this is a cost that should be borne by the practice, which makes the decision on how many physicians have log-in privileges. A laboratory may, however, pay such charges to its own IT/LIS vendors who have no contractual relationship with either the EHR vendor or the referring provider even though the results of their work go to an EHR.

What Is Allowed?

Labs operating in New York state may provide limited types of software and hardware that facilitate test ordering and the transfer and storage of laboratory-generated data, according to the Sept. 27 letter. For example, labs may:

1 Interface their LIS to the client's existing EHR to enable seamless test ordering and results reporting and facilitate other lab-related functions (see No. 2 below) and may assume, as a cost of doing business, the cost of a such a limited interface.

2 Provide a practitioner with computer hardware, software, and information technology training and supplies that are restricted to lab-related functions that enable a practitioner to (a) order tests from the lab, including access to a directory of services (*i.e.*, specimen type, collection container, and test information); (b) receive, access, print, and store test results received from the lab, including storing cumulative results for individual patients; (c) transmit data necessary for the lab to prepare requisitions and generate bills, invoices, or claims for reimbursement; and (d) transfer lab data received from the lab to any computer system maintained by the practitioner.

3 Provide computer hardware and software as noted above that also contains functionality that permits a practitioner to make referrals to other laboratories and/or provides access to other laboratories' Internet portals.

4 Provide to a Regional Health Information Organization (RHIO) or health information exchange (HIE) computer equipment and supplies, information technology, and software in accordance with the requirement in No. 2 above. Labs may not contribute to the RHIO's or HIE's acquisition costs for EHR components, including software interfaces, or a practitioner's costs of participation unless in accordance with the requirements in No. 2 above.

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American Medical Association, the American Hospital Association, and the American Health Care Association, among others.

In talks with CMS officials, they argued that most tests are requested via paper requisitions or fax by a nurse or office staff at the direction of the physician, but most are never signed. Under the new policy, the requisition would have to be returned to the physician or NPP to sign, a burdensome added step for nursing homes, home health agencies, and other health facilities where a physician or NPP is not on-site. Further, labs have no way to enforce the requirement and are the only provider at financial risk if requisitions are not signed.

Providers also took their case to Capitol Hill, lobbying members of Congress about the negative impact the policy would have on timely patient care. The lab industry mounted a three-day lobbying effort to get members of the House and Senate to sign on to a bipartisan letter to CMS chief Donald Berwick, M.D., expressing their concerns.

The House letter with 85 signatories was sent on Feb. 10 and the Senate letter with 34 signatories on Feb. 11 (copies of the letters are posted at *clinical-labs.org*). Lawmakers said, "Additional time is necessary for CMS to work with the laboratory, physician, hospital, and long-term care communities to put in place safeguards to ensure patient care is not negatively affected, allay concerns on possible payment complications stemming from this new requirement, and ensure a streamlined process for health care providers."

The letters noted that electronic medical records hold "the potential to transform the process and documentation of orders and requisitions, offering CMS access to standardized documentation of the physician's orders."

In commenting on the turnabout, attorney Robert Mazer with Ober/Kaler (Baltimore) told G-2 Reports, "It's great news for the industry." Though not involved in the lobbying blitz, Mazer said, "It demonstrates what can be accomplished when laboratories offer sound reasons why a particular policy would not accomplish what it was intended to do. Let's also take off our collective hats to CMS for listening to the industry's points and recognizing that the policy that it had initially developed may not have been the best."

The controversial physician signature requirement reversed longstanding policy, finalized in a 2001 rule developed by a negotiated rulemaking, that while a signature is one way to document who ordered a lab test, it is not the only permissible way as long as the order is documented in an alternate format, such as the beneficiary's medical record. This policy had been reiterated in CMS manual issuances as late as March 10, 2010. But in July 2010 the agency announced the new requirement in the proposed 2011 physician fee schedule and adopted it without modification in the final 2011 rule.

Key Features of the Controversial Policy

The physician or NPP signature requirement applies to test requests made on paper forms, not to tests requested electronically or by telephone. If the request is made by telephone, both the treating physician or practitioner, or his or her office, and the testing facility must document the call in their respective copies of the beneficiary's medical records.

A requisition is the actual paperwork, such as a form, provided to a clinical diagnostic laboratory that identifies the tests to be performed for a patient. Physicians are not required to use one. They may use an "order," which CMS defines as "a communication from the treating physician or practitioner requesting that a diagnostic test be performed." This can be an annotated medical record or a documented telephone request.

The policy applies to clinical laboratory services payable under the Part B lab fee schedule. It does not apply to pathology services payable under the Part B physician fee schedule.

Medicare Claims Advisory

Increase in Travel Allowance Announced for 2011

In a Feb. 11 transmittal to local contractors, the Centers for Medicare and Medicaid Services (CMS) announced an increase in the Medicare travel allowance payable when it is medically necessary for a laboratory technician to collect a specimen from a nursing home or homebound beneficiary.

The new rates for the trip fee codes payable under the Part B lab fee schedule are effective Jan. 1. The implementation date for contractors is March 14 (Change Request 7313, Feb. 11, 2011).

- ❏ P9603 96 cents per-mile trip basis
- ❏ P9604 $9.60 per flat-rate trip basis

The rates in effect last year for P9603 and P9604 were 95 cents and $9.50, respectively.

Payment Policy

Payment of the travel allowance is made only if a specimen collection fee is payable for draws from homebound or nursing home beneficiaries.

P9603 is used in situations where the average trip to the patients' homes is longer than 20 miles round trip, and it is to be prorated in situations where specimens are drawn from non-Medicare patients in the same trip.

The allowance per mile was computed using the federal mileage rate of 51 cents per mile plus an additional 45 cents per mile to cover the technician's time and travel costs. Contractors have the option of establishing a higher per-mile rate in excess of the minimum 96 cents per mile if local conditions warrant it.

Contractors have discretion to choose either a mileage basis or a flat rate and how to set each type of allowance. Because of audit evidence that some laboratories abused the per mileage fee basis by claiming travel mileage in excess of the minimum distance necessary, many contractors established local policy to pay based on a flat-rate basis only.

Under either method, when one trip is made for multiple specimen collections (for example, at a nursing home), the travel payment is prorated based on the number of specimens collected on that trip for both Medicare and non-Medicare patients either at the time the claim is submitted by the lab or when the flat rate is set by the contractor.

The minimum mileage rate will be reviewed and updated throughout the year, CMS said, as well as in conjunction with the lab fee schedule, as needed.

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