Final 60-Day Overpayment Rule Cuts Look-Back Period, Raises Stakes for Compliance

In the final regulation on the Medicare 60-day overpayment refund mandate, which was published in the Feb. 12 Federal Register, CMS drew a straight line to compliance programs, saying “providers and suppliers have a clear duty to undertake proactive activities to determine if they have received an overpayment or risk potential liability for retaining such overpayment.” The regulation also gives providers more breathing room to “identify” and “quantify” an overpayment before reporting it and reduces the number of years they must look back in time for an overpayment from 10 to six — although there’s some controversy on this issue.

The long-awaited regulation interprets Sec. 6402(a) of the Affordable Care Act, which requires Medicare and Medicaid overpayment returns 60 days from the day they are identified or from the date any corresponding cost report is due, whichever is later.

There has been confusion among providers about when they have officially “identified” an overpayment and therefore started the 60-day countdown. According to the final rule, a “person has identified an overpayment when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment.” That’s a stark contrast to continued on p. 6

Hospitals Face Four Types of Meaningful Use Audits; Documentation Is Saving Grace

With four different types of meaningful use audits in progress, the odds are good that hospitals and physicians will face an evaluation of their compliance with the electronic health record (EHR) incentive program. The federal government has given providers $40 billion to adopt certified EHRs, and Medicaid and Medicare auditors are looking at whether that money was spent properly — and taking it back if it wasn’t.

Although meaningful use will eventually be absorbed into the Merit-Based Incentive Payment System (MIPS) enacted in the 2015 Medicare Access and CHIP Reauthorization Act (MACRA), the requirements governing meaningful use of EHRs are still in effect. How they mesh will become clearer when the MIPS regulation comes out in April. But MIPS won’t slow the audit juggernaut, which puts at risk years of meaningful use money received by “eligible hospitals” and “eligible professionals” (e.g., physicians), according to Mike Orr, a director at BKD LLP, and Travis Skinner, a senior managing consultant at BKD.

Because hospitals and physicians are required to keep auditable records for six years after attesting to meaningful use of certified EHRs, “we are thinking these audits will be around for a while,” Orr says.

The EHR incentive program — created by the HITECH Act in the 2009 stimulus law — uses carrots and sticks to get providers on board with the technology. Hospitals
and physicians started receiving Medicare and Medicaid bonuses for becoming meaningful users of certified EHR technology in 2011 and will pay penalties if they aren’t. Compliance is evaluated after the fact — by audits. To get incentive payments annually, hospitals and physicians have to answer some yes/no questions about their use of EHRs to satisfy meaningful use objectives, enter some data on the objectives, agree to keep all required documentation and sign an attestation that it’s all true. If the audits back them up, the money stays put.

Meaningful use requirements have evolved over time. For example, in Stage 2 of meaningful use for 2014, hospitals had to satisfy 16 core objectives, such as using computerized provider order entry for medication, lab and radiology orders; three of six menu objectives, such as using the EHRs for imaging results and family health history; and 16 of 29 clinical quality measures, such as documenting that aspirin was prescribed to heart attack patients. Eligible physicians had their own core and menu objectives. For Modified Stage 2, which covers 2015 through 2017, CMS consolidated core and menu objectives into a single set of 10 objectives that applies to all hospitals and physicians. They include patient-specific education, medication reconciliation and secure messaging.

The audits now underway look back at prior years’ compliance with meaningful use, and the auditors may look at multiple years during the same audit. “Everything’s up for grabs,” Orr says. A great unknown is the outcome of new audits under the “flexibility rule,” which allowed hospitals and physicians to attest to a reduced level of meaningful use of certified EHRs for 2014.

Updates on the Four Audits

Here is an update on the four kinds of audits underway, according to Orr and Skinner:

(1) Medicare all-or-nothing meaningful use audits:
In April 2011, CMS hired an auditor, Figliozzi and Co. of Garden City, N.Y., to audit EHR incentive payments. Hospitals and physicians lose their entire meaningful use payment for the audit period if there is any noncompliance (RMC 3/3/14, p. 1). Orr and Skinner say hospitals often run afoul of the yes/no questions they answer on the attestation. One hospital attested that it electronically transmitted immunization data to the state public health agency, but it turned out the lab director was merely keying data into the state website. “That doesn’t qualify as an electronic transfer requirement, so the hospital didn’t meet the measure it attested to,” Skinner says. A nurse at another hospital printed discharge instructions from the EHR system, and that won’t fly because a printout is not the same as an interoperable electronic record, Orr says.

Then there was the hospital that didn’t buy interfaces for public health reporting — syndromic surveillance, immunization data and lab reporting — because its state didn’t have the capacity to receive the data electronically. The hospital figured it might as well save money since CMS grants exemptions when states can’t accept EHR data. “But that meant the hospital didn’t have a fully certified meaningful use system,” and it flunked the Figliozzi audit, Skinner says. Public health reporting got a different hospital dinged in an audit when it attested that it qualified for the public-reporting exemption for immunizations, but Figliozzi wanted proof. It turned out the state exemption letter applied to the previous year.

Security risk assessments (SRAs) “have been a thorn in many sides,” Orr says. Some hospitals did a meaningful use SRA in 2011 but never updated it. “Each year is not tied to another year,” he explains. Hospitals also may forget to do an SRA for their physician practice, which is required if the practice received separate meaningful use money. Orr says some hospitals are under the impression that meaningful use SRAs are the same as HIPAA risk assessments, but that’s not true. The former is a subset of the latter. For example, HIPAA risk analysis requires

Report on Medicare Compliance (ISSN: 1094-3307) is published 45 times a year by Atlantic Information Services, Inc., 1100 17th Street, NW, Suite 300, Washington, D.C. 20036, 202-775-9008, www.AISHealth.com. Copyright © 2016 by Atlantic Information Services, Inc. All rights reserved. On an occasional basis, it is okay to copy, fax or email an article or two from RMC. But unless you have AIS’s permission, it violates federal law to make copies of, fax or email an entire issue, share your AISHealth.com subscriber password, or post newsletter content on any website or network. To obtain our quick permission to transmit or make a few copies, or post a few paragraphs of RMC at no charge, please contact Eric Reckner (800-521-4323, ext. 3042, or erreckner@aishealth.com). Contact Bailey Sterrett (800-521-4323, ext. 3034, or bsterrett@aishealth.com) if you’d like to review our very reasonable rates for bulk or site licenses that will permit weekly redistributions of entire issues. Contact Customer Service at 800-521-4323 or customerserv@aishealth.com.

Report on Medicare Compliance is published with the understanding that the publisher is not engaged in rendering legal, accounting or other professional services. If legal advice or other expert assistance is required, the services of a competent professional person should be sought.

Managing Editor, Nina Youngstrom; Assistant Editor, Angela Maas; Contributing Editor, Francie Ferrand; Executive Editor, Jill Brown; Publisher, Richard Bielt; Marketing Director, Donna Lawton; Fulfillment Manager, Tracey Filar Abwood; Production Editor, Carrie Epps.

Subscriptions to RMC include free electronic delivery in addition to the print copy, e-Alerts when timely news breaks, and extensive subscriber-only services at www.AISHealth.com that include a searchable database of RMC content and archives of past issues.

To order an annual subscription to Report on Medicare Compliance ($764 bill me; $664 prepaid), call 800-521-4323 (major credit cards accepted) or order online at www.AISHealth.com.

Subscribers to RMC can receive 12 Continuing Education Credits per year, toward certification by the Compliance Certification Board. Contact CCB at 888-580-8373.

Report on Medicare Compliance (ISSN: 1094-3307) is published 45 times a year by Atlantic Information Services, Inc., 1100 17th Street, NW, Suite 300, Washington, D.C. 20036, 202-775-9008, www.AISHealth.com. Copyright © 2016 by Atlantic Information Services, Inc. All rights reserved. On an occasional basis, it is okay to copy, fax or email an article or two from RMC. But unless you have AIS’s permission, it violates federal law to make copies of, fax or email an entire issue, share your AISHealth.com subscriber password, or post newsletter content on any website or network. To obtain our quick permission to transmit or make a few copies, or post a few paragraphs of RMC at no charge, please contact Eric Reckner (800-521-4323, ext. 3042, or erreckner@aishealth.com). Contact Bailey Sterrett (800-521-4323, ext. 3034, or bsterrett@aishealth.com) if you’d like to review our very reasonable rates for bulk or site licenses that will permit weekly redistributions of entire issues. Contact Customer Service at 800-521-4323 or customerserv@aishealth.com.

Report on Medicare Compliance is published with the understanding that the publisher is not engaged in rendering legal, accounting or other professional services. If legal advice or other expert assistance is required, the services of a competent professional person should be sought.

Managing Editor, Nina Youngstrom; Assistant Editor, Angela Maas; Contributing Editor, Francie Ferrand; Executive Editor, Jill Brown; Publisher, Richard Bielt; Marketing Director, Donna Lawton; Fulfillment Manager, Tracey Filar Abwood; Production Editor, Carrie Epps.

Subscriptions to RMC include free electronic delivery in addition to the print copy, e-Alerts when timely news breaks, and extensive subscriber-only services at www.AISHealth.com that include a searchable database of RMC content and archives of past issues.

To order an annual subscription to Report on Medicare Compliance ($764 bill me; $664 prepaid), call 800-521-4323 (major credit cards accepted) or order online at www.AISHealth.com.

Subscribers to RMC can receive 12 Continuing Education Credits per year, toward certification by the Compliance Certification Board. Contact CCB at 888-580-8373.
penetration testing and port analysis, which aren’t part of meaningful use.

How well hospitals fare in the Figliozzi audits depends on their documentation, Skinner says. “The biggest issue we run into is a lot of facilities turn meaningful use over to their IT department,” he explains. “But this is not an IT audit. It’s a meaningful use audit done by CPAs. They are box checkers, and they don’t have an IT background. They ask, ‘what paper do you have to prove you have all the meaningful use requirements?’”

Sometimes a hospital or physician has dropped the ball on a measure they attested to, but it turns out they unwittingly complied with another measure, Orr and Skinner say. Hopefully, Figliozzi will accept a switch.

And now the first flexibility rule audits have begun. How hospitals and physicians will fare is anyone’s guess because they had to use their best judgment about what passes muster. But there was no way to get advance approval for the lower meaningful use criteria, Orr and Skinner note. The reason CMS established the flexibility rule is that thousands of EHR vendors didn’t update their software in time for hospitals and physicians to comply with Stage 2 of meaningful use, Skinner explains. “If it’s not your fault, you can flex out to lesser criteria,” Orr says. “But if you were flexing out because you couldn’t meet one of the measures,” you’re out of luck with Figliozzi.

(2) Medicaid audits by the HHS Office of Inspector General: They are deemed a “high priority” through 2018, and OIG is now at work in Pennsylvania. It has already published seven reports on whether state Medicaid agencies properly doled out meaningful use money, which comes entirely from the federal government. The findings: No hospitals were overpaid or underpaid in Florida or Washington, D.C., but states overpaid hospitals in Arkansas, Delaware, Louisiana, Massachusetts and Texas — usually much more than they underpaid them — and must get that money back. In Texas, for example, OIG said 26 hospitals were overpaid $13.9 million in meaningful use money in 2011 and 2012. OIG also issued one report on Medicaid meaningful use payments to eligible professionals in Oklahoma, which found the state overpaid $888,250.

(3) Audits of “adopt, implement or upgrade” (AIU) Medicaid money: This is funding that hospitals and physicians got from CMS in the early days of the EHR incentive program even if they were not yet meaningful users. “[CMS] wanted to get money in the hands of people. They were trying to encourage the adoption of EHRs,” Skinner says. The use of that money is under scrutiny by state Medicaid agencies, which often use third-party vendors to conduct audits. “Those AIU dollars have separate criteria,” he says. For example, for AIU compliance, the state asks the hospital or physician to show it has at least 10% Medicaid volume.

(4) Medicare administrative contractor (MAC) cost-report audits: Every EHR incentive payment received by a hospital will face a desk review, in-house audit or on-site audit, Orr says. The MAC will adjust incentive payments based on other costs reported on the cost report, such as the number of discharges, bad debt and charity care. The problem has been that hospitals may disregard letters they get after the audit, he says. The letters are not signed by a person — they simply say “sincerely, EHR HITECH Incentive Payment Center” — yet they demand immediate repayment. “Most people thought they were being scammed,” he explains, and threw the letter away. On a happier note, hospitals may be able to turn an audit frown upside down. There are “positive adjustment opportunities,” such as Part C days, total days and charity care, Orr says.

Contact Orr at morr@bkd.com and Skinner at tskinner@bkd.com.

**Rebilling, Registries for ICDs, Newly Covered Watchman Pose Risks**

Hospitals may find claims for some expensive procedures denied because there’s no proof in the medical records that the patients were entered into a registry. That’s happening now with implantable cardiac defibrillators (ICDs) and may happen in the near future with the Watchman device now that CMS has given the go-ahead for Medicare coverage.

CMS requires hospitals — as a condition of payment — to report their ICD procedures to the ICD Registry, a national databank, for primary-prevention patients. There’s not enough information on claims to verify that patients had the clinical conditions required for a primary indication, which is covered by Medicare, and the elaboration in the registry enables CMS to evaluate compliance with coverage conditions. Most hospitals also submit information for secondary indications, although it’s not mandated.

“If patients are getting defibrillators for primary prevention of sudden cardiac death, and they have not yet had a heart attack or a serious arrhythmia but are at high risk for one, CMS wants confirmation they are enrolled in a registry,” said Ronald Hirsch, M.D., vice president of education and regulations at Accretive Physician Advisory Services, during a Feb. 4 webinar on 2016 risk areas sponsored by RACMonitor.com. “It must be placed into every single chart. Find out if you are doing this, and, if not, establish a process.” He said that Medicare administrative contractors are applying this requirement “stringently.” Medicare pays hospitals $30,000 to $45,000 for Medicare coverage.
for procedures to implant defibrillators, so recoupment would hit hard.

Registering patients who receive the Watchman is a requirement spelled out in the newly finalized decision memo for percutaneous left atrial appendage closure therapy (for which the Watchman, developed by Boston Scientific, is the only FDA-approved device). This means hospitals can start implanting them — as soon as the registry is established, Hirsch said. CMS also moved Watchman devices into a new, more lucrative DRG in the 2016 inpatient prospective payment system (IPPS) regulation, Hirsch said. They should be billed under DRGs 274 (percutaneous intracardiac procedures without major complications and comorbidities) and 273 (the same, but with major complications and comorbidities).

The Watchman is an alternative to long-term use of anti-coagulant drugs, and some cardiologists are clamoring to implant it (RMC 1/11/16, p. 1), Hirsch said. It's only for patients with non-valvular atrial fibrillation who meet other criteria, according to the decision memo, which is different than the proposed version. For example, CMS does not require warfarin to be contraindicated. Hospitals also have to ensure physicians who implant Watchman devices are properly trained and supervised. They must have done 25 prior transseptal punctures and complete a minimum number of procedures every two years, according to Hirsch.

Hospitals should keep their eyes on other procedures that are covered only in certain circumstances (e.g., clinical trials or required clinical registries). "Medicare has many procedures that are approved but only under coverage with evidence development," Hirsch cautioned. "CMS says, 'we will allow it to happen but only in a situation where data is collected so we can look at the overall efficacy of the procedures.'" Hospitals may be surprised by what's on this list. It includes cochlear implants, off-label use of colorectal cancer drugs, home oxygen for chronic obstructive pulmonary disease (without hypoxia) and transcatheter mitral valve repair. (See the list at http://tinyurl.com/gv9sjdy.)

Rebilling Medicare Part B after hospitals self-deny Part A claims or auditors deny them persists as a risk because of misunderstandings about the mechanics, Hirsch said. CMS allows A/B rebilling only when the inpatient level of care is medically unnecessary — not because the services themselves are medically unnecessary, he noted. Whether hospitals rebill after self-deny their claims — they realize an admission wasn’t reasonable and neces-

### New Data on RAC Error Findings, Top Risk Areas

<table>
<thead>
<tr>
<th>Medicare Fee for Service National Recovery Audit Program (July 1, 2015 – September 30, 2015)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OVERPAYMENTS COLLECTED</td>
</tr>
<tr>
<td>Region A: Performant</td>
</tr>
<tr>
<td>Region B: CGI</td>
</tr>
<tr>
<td>Region C: Connolly</td>
</tr>
<tr>
<td>Region D: HDI</td>
</tr>
<tr>
<td>Nationwide Totals</td>
</tr>
</tbody>
</table>

**NOTE:** Figures rounded to nearest tenth; nationwide figures rounded based on actual collections. Figures provided in millions. All correction data current through September 30, 2015.

### TOP ISSUE PER REGION

**Region A:** MS-DRG Validation: Cardiac Valve Procedures: (complex review) MS-DRG Validation requires that diagnostic and procedural information and the discharge status of the beneficiary, as coded and reported by the hospital on its claim, matches both the attending physician description and the information contained in the beneficiary's medical record.

**Region B:** OP Rituximab 100mg Dose vs. Units Billed: (complex review) Rituximab, (Rituxan), 100mg (J9310) should be billed one (1) unit for every 100mg per patient administered. Hospitals need to ensure that units of drugs administered to patients are accurately reported in terms of dosage specified in the full HCPCS code descriptor.

**Region C:** Excessive or Insufficient Drug Units Billed - Outpatient: (complex review) Drugs and Biologicals should be billed in multiples of the dosage specified in the HCPCS code long descriptor. The number of units billed should be assigned based on the dosage increment specified in that HCPCS long descriptor, and correspond to the actual amount of the drug administered to the patient, including any appropriate, discarded drug waste.

**Region D:** Gastrointestinal Procedures MSDRGS 326-358, 405-416, 417-425: (complex review) MS-DRG Validation requires that diagnostic and procedural information and the discharge status of the beneficiary, as coded and reported by the hospital on its claim, matches both the attending physician description and the information contained in the beneficiary's medical record.

**SOURCE:** CMS, http://tinyurl.com/gnpeybr

Web addresses cited in this issue are live links in the PDF version, which is accessible at RMC's subscriber-only page at http://aishealth.com/newsletters/reportonmedicarecompliance.
sary — or an auditor denies them, they are subject to the one-year timely filing deadline, which means the Part B claim must be submitted within one year of the original date of service.

Hospitals run into trouble if they self-denial Part A claims and rebill them without review by a physician member of the utilization review (UR) committee, Hirsch said. “Many hospitals are shocked to hear that self-denials must go through the UR process,” he said. He often sees case managers unilaterally deciding to self-denial and rebill without UR physician review, attending physician contact or patient notification. But that, he said, is non-compliant.

In the 2014 IPPS, CMS set forth the process for reviewing admissions for the medical necessity of the level of care. If patients already have been discharged when their admissions are declared improper, the admissions must be reviewed by UR physicians, Hirsch said. When one UR physician agrees that an outpatient setting was more appropriate, he or she discusses it with the attending physician on the case. If the attending physician concurs, rebilling moves forward. If the attending physician disagrees or is unresponsive, a second UR physician may give consent to rebill. Patients must be notified within two days of the decision to rebill.

What can be rebilled to Part B after a Part A denial depends on when the admission order was signed, Hirsch said. Services provided before the admission order are billed as Part B outpatient services (e.g., emergency room services). Services provided after the admission order are billed to inpatient Part B (e.g., procedures). Hospitals “don’t get paid for observation unless patients got it prior to the inpatient order when rebilling an inpatient admission that was not medically necessary,” he said. And observation is billable only if there was an order for observation.

If hospitals self-denial claims for medically unnecessary services, they can’t rebill Medicare in the sweeping way that Medicare intended in the 2014 IPPS. But they can rebill Part B for ancillary services described in the Medicare Benefit Policy Manual (Chapter 6, Sec. 10.2). And no review by the UR committee is necessary, Hirsch noted.

Physicians shouldn’t be alarmed by self-denials and rebilling because they don’t endanger professional fees.

---

New Data on RAC Error Findings, Top Risk Areas (continued)

| Medicare Fee for Service National Recovery Audit Program (October 1, 2015 – December 31, 2015) |
|-------------------------------------------------|---------------------------------|---------------------------------|-----------------|-----------------|
| Region A: Performant | $18.27 | $6.40 | $24.67 | $24.67 |
| Region B: CGI | $16.29 | $1.58 | $17.87 | $17.87 |
| Region C: Connolly | $53.90 | $21.01 | $74.91 | $74.91 |
| Region D: HDI | $43.84 | $10.09 | $53.93 | $53.93 |
| Nationwide Totals | $132.30 | $39.08 | $171.38 | $171.38 |

**NOTE:** Figures rounded to nearest tenth; nationwide figures rounded based on actual collections. Figures provided in millions. All correction data current through December 31, 2015.

**TOP ISSUE PER REGION**

Based on collected amounts from October 1, 2015, through December 31, 2015

- **Region A:** DMEPOS While Inpatient: (automated review) A supplier may deliver a DMEPOS item to a patient in a hospital or nursing facility for the purpose of fitting or training the patient in the proper use of the item. This may be done up to two (2) days prior to the patient’s anticipated discharge to their home. The supplier should bill the date of service on the claim as the date of discharge and shall use the place of service (POS) as 12 (patient’s home). The item must be for subsequent use in the patient’s home. No billing may be made for the item on those days the patient was receiving training or fitting in the hospital or nursing facility.

- **Region B:** OP Rituximab 100mg Dose vs. Units Billed: (complex review) Rituximab, (Rituxan), 100mg (J9310) should be billed one (1) unit for every 100mg per patient administered. Hospitals need to ensure that units of drugs administered to patients are accurately reported in terms of dosage specified in the full HCPCS code descriptor.

- **Region C:** MMR of Therapy Claims Above $3,700 Threshold (OP): (complex review) CMS determines an annual per beneficiary therapy cap amount for each calendar year. Exceptions to the therapy cap are allowed for reasonable and necessary therapy services. Per beneficiary, services above $3,700 for PT and SLP services combined and/or $3,700 for OT services are subject to manual medical review.

- **Region D:** O.R. Procedures Unrelated to Principal Diagnosis MS-DRGs 981-989: (complex review) MS-DRG Validation requires that diagnostic and procedural information and the discharge status of the beneficiary, as coded and reported by the hospital on its claim, matches both the attending physician description and the information contained in the beneficiary’s medical record.

**SOURCE:** CMS, http://tinyurl.com/js45rr7

---

Subscribers who have not yet signed up for Web access — with searchable newsletter archives, Hot Topics, Recent Stories and more — should click the blue “Login” button at www.AISHealth.com, then follow the “Forgot your password?” link to receive further instructions.
Patients’ status is unaffected, which means physician reimbursement doesn’t change, Hirsch said.

Contact Hirsch at rhirsch@accretivehealth.com. View the decision memo for the Watchman device at http://tinyurl.com/h9vncpw. 

Hospitals Will Have Day in Court Over Medicare Appeals Backlog

Hospitals again will have a shot at persuading a federal court to get administrative law judges (ALJs) to rule on appeals of Medicare claim denials a lot faster.

The U.S. Court of Appeals for the District of Columbia on Feb. 9 sent the American Hospital Association’s (AHA) case against CMS (No. 15-5015) back to the U.S. District Court for the District of Columbia to reconsider whether to issue a writ of mandamus to compel the agency to resolve the Medicare appeals backlog.

AHA had sued CMS over the length of time it takes for the Office of Medicare Hearings and Appeals (OMHA) to hold hearings and make decisions on Medicare appeals. On average, it takes 20 months for a provider to get a hearing with an ALJ, says Atlanta attorney Ross Burris, with Polsinelli. As much as three years can elapse from the time a claim is denied to the time the appeals process concludes, he says. “OMHA typically says that it doesn’t have the staff or operational capacity to handle its workload,” he notes.

In the lawsuit, AHA pointed to the statutory deadlines for each level of appeal and argued that these were “mandatory.” For example, ALJs are required to conduct hearings and render decisions within 90 days. But AHA didn’t get its way in 2014. In granting CMS’s motion to dismiss for lack of jurisdiction, the district court ruled that “the constraints of budgetary concerns and competing agency priorities” outweighed other factors. The appeals court, however, noted the massive and increasing number of pending appeals and described the situation as a “systemic failure” that causes all appeals to be decided well after the statutory deadlines. Given the unique circumstances, it concluded that AHA had met the three jurisdictional thresholds for mandamus: (1) a clear and indisputable right to relief, (2) the government agency or official is violating a clear duty to act, and (3) no adequate alternative remedy exists. On remand, the district court must determine whether “compelling equitable grounds” now exist and “whether the agency’s delay is so egregious as to warrant mandamus.”

The Court of appeals also set forth a number of factors both for and against issuing the writ. It suggested that the district court “might find it appropriate to issue a writ of mandamus ordering the Secretary to cure the systemic failure to comply with the deadlines,” or it could allow the agency and Congress to make “significant” progress toward a resolution and submit status reports to the court. But, the court concluded, “In the end, although courts must respect the political branches and hesitate to intrude on their resolution of conflicting priorities, our ultimate obligation is to enforce the law as Congress has written it. Given this, and given the unique circumstances of this case, the clarity of the statutory duty likely will require issuance of the writ if the political branches have failed to make meaningful progress within a reasonable period of time — say, the close of the next full appropriations cycle.”

“It’s just a first step for the hospitals, but they were denied the first step previously,” Burris says. “Now they have a chance to convince the court they need to have hearings [within in 90 days] partly because of the financial impact and uncertainty with this much money tied up in appeals.”

Contact Burris at rburris@polsinelli.com. View the decision at http://tinyurl.com/zmxxruk.

CMS Finalizes 60-Day Rule

continued from p. 1

the proposed rule, which came out exactly four years earlier (RMC 2/20/12, p. 1) and stated that overpayments are identified when the provider had actual knowledge of the existence of the overpayment or acted in reckless disregard or deliberate ignorance of the overpayment.

“The clock doesn’t start ticking until you confirm you have an overpayment and quantify the overpayment,” says Atlanta attorney Sara Kay Wheeler, with King & Spalding. She thinks it will comfort providers because they have more time to conduct a reasonable investigation before turning on the timer. “It’s not a sprint, but it’s not a Sunday walk in the park,” adds Tony Maida, former deputy chief of the HHS Office of Inspector General’s Administrative and Civil Remedies Branch.

The look-back period was reduced in the final rule. There was a reviled 10-year look-back period in the
proposed rule, which required providers to return overpayments if they were “within 10 years of the date the overpayment was received.” CMS cut it to six years, but Wheeler thinks that’s the absolute maximum. “I don’t believe it would be CMS’s position you had to go back six years every time,” she says. “But you have to use reasonable diligence in every case.” For example, if a hospital determined a 2014 software conversion caused an overpayment, the audit may stop there.

There’s a trap in the six-year look-back period, contends Minneapolis attorney David Glaser, with Fredrikson & Byron. It’s inconsistent with CMS’s own claims reopening rules, which give Medicare contractors 48 months to adjust claims “for good cause” (42 CFR Sec. 405.980 and Sec. 1870 of the Social Security Act), he says. Does the overlap mean that providers have to go back further than Medicare auditors to voluntarily refund money? And if the auditors put providers on notice of an overpayment, the audit may stop there.

“That is insane,” Glaser says. “There is some figuring out to be done. One possible answer? After 48 months, an incorrect payment isn’t an ‘overpayment’ unless there is ‘fraud or similar fault.’”

In adopting a standard of “reasonable diligence” for identifying and quantifying overpayments through a “timely, good-faith investigation,” CMS puts brackets around that as well. The preamble states that an investigation should take “at most 6 months from receipt of the credible information, except in extraordinary circumstances,” a replacement for the “all deliberate speed” language in the proposed rule. An example of extraordinary circumstances would be overpayments stemming from violations of the Stark law that were submitted to the CMS Self-Referral Disclosure Protocol.

“They are giving you a benchmark,” Wheeler says. CMS is telling providers to try to get the investigation done in six months, and, if they can’t, they must document why, she says. Having that time before the clock starts ticking on the 60 days will help providers sort things out, some lawyers say. “There’s nothing worse than going to the government with the wrong information,” says Maida, with McDermott, Will & Emery in New York City.

But Denver attorney Jeffrey Fitzgerald doesn’t think CMS has the authority to set outside timelines. However, “from a compliance perspective, it might be a good objective to have all compliance reviews completed in six months,” says Fitzgerald, with Polsinelli.

The final rule spoke to the futility of identifying overpayments without a compliance program.

“I’m not sure CMS has ever articulated as strongly that it believes providers should have compliance

---

### CMS Transmittals and Federal Register Regulations

**Feb. 5 – Feb. 11**

Live links to the following documents are included on RMC’s subscriber-only Web page at www.AISHealth.com. Please click on “CMS Transmittals and Regulations” in the right column.

**Transmittals**

(R) indicates a replacement transmittal.

**Pub. 100-03, National Coverage Determinations**

- Screening for Cervical Cancer With Human Papillomavirus Testing — National Coverage Determination, Trans. 189NCD, CR 9434 (Feb. 5; eff. July 9, 2015; impl. multiple dates)
- Screening for the Human Immunodeficiency Virus Infection, Trans. 190NCD, CR 9403 (Feb. 5; eff. April 13, 2015; impl. multiple dates)

**Pub. 100-04, Medicare Claims Processing Manual**

- New Condition Code for Reporting Home Health Episodes With No Skilled Visits, Trans. 3457CP CR 9474 (Feb. 5; eff. July 1; impl. July 5, 2016)
- Screening for Cervical Cancer With Human Papillomavirus Testing — National Coverage Determination, Trans. 3460CP CR 9434 (Feb. 5; eff. July 9, 2015; impl. multiple dates)
- Screening for the Human Immunodeficiency Virus Infection, Trans. 3461CP CR 9403 (Feb. 5; eff. April 13, 2015; impl. multiple dates)
- April 2016 Quarterly Average Sales Price Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files, Trans. 3450CP CR 9536 (Feb. 4; eff. April 1; impl. April 4, 2016)

**Pub. 100-08, Medicare Program Integrity Manual**

- Update to Pub. 100-08, Chapter 15, Trans. 636PI, CR 9930 (Feb. 4; eff./impl. March 4, 2016)

**Pub. 100-20, One-Time Notification**

- Accredited Standards Committee X12 Healthcare Claims Acknowledgement (277CA) Flat File Update, Trans. 1609OTN, CR 9454 (Feb. 4; eff. July 1; impl. July 5, 2016)
- Advance Care Planning Services furnished by Rural Health Clinics, Trans. 1615OTN, CR 9503 (Feb. 4; eff. Jan. 1; eff. July 1; impl. July 1, 2016)

**Federal Register Regulations**

**Final Rule**

programs proactively be looking for issues and that not having a compliance program could result in being found to not exercise reasonable diligence,” Maida says. He cautions that whistleblowers will be all over this rule, with cases focused on the processes that providers had in place to review issues that came to their attention and whether they satisfied the reasonable diligence standard (RMC 8/10/15, p. 1). That’s a departure from false claims cases based on billing and coding violations, he noted.

The regulation, which takes effect in 30 days, isn’t retroactive, notes Fitzgerald. “If you complete an audit and refund before 30 days from [Feb. 12], then you don’t apply the final rule,” he says. “You use the four-year claims reopening rules.”

Fitzgerald summed up some of the other key parts:
◆ CMS rejected any notion of a de minimis overpayment, leniency for small overpayments and offsetting overpayments with underpayments.
◆ CMS clarified that an overpayment is the difference between what Medicare paid and what Medicare should have paid.
◆ Providers should not submit contested or disputed refunds. They have to come to their own conclusions about whether an overpayment exists.
◆ Providers may ask their Medicare administrative contractors to use the claim adjustment process instead of writing a check to refund overpayments.
◆ The regulation applies to only Medicare — not Medicaid.

View the rule at http://federalregister.gov/a/2016-02789.

For more information, contact Maida at tmaida@mwe.com, Fitzgerald at JFitzgerald@polsinelli.com, Wheeler at SKWheeler@KSLAW.com and Glaser at dglaser@fredlaw.com.

NEWS BRIEFS

◆ Westfield, N.J., physician Labib E. Riachi and two of his companies were accused of submitting millions of dollars of false Medicare and Medicaid claims for diagnostic tests, the U.S. Attorney’s Office for the District of New Jersey said Feb. 19. Riachi and his companies, Riachi, Inc. and the Center for Advanced Pelvic Surgery, LLC, allegedly billed for diagnostic tests that were never performed, including anorectal manometry, an invasive diagnostic test, and electromyography. The false claims complaint also alleged the defendants billed for physical therapy services performed by unqualified personnel.

For more information, visit http://tinyurl.com/zb2gaxs.

◆ Promise Hospital of Ascension, a 54-bed transitional care hospital in Gonzales, La., was overpaid $465,000 because it incorrectly reported kwashiorkor on inpatient claims, the HHS Office of Inspector General (OIG) says in a new report (A-03-15-00007). OIG reviewed 62 claims submitted by the hospital over four years with ICD-9 code 260 (kwashiorkor), which is severe protein malnutrition, and concluded the hospital “should have used codes for other forms of malnutrition or no malnutrition code at all.” David Armstrong, general counsel and chief compliance officer of Promise Healthcare, disagreed with the findings. “Promise believes protein malnutrition was documented in the medical record, supported by the treatment provided to the patient, and coded according to Promise’s good faith and reasonable interpretation of the official ICD-9-CM instructions,” he stated in a letter responding to the report. “Accordingly, Promise believes that the claims contained in the audit were appropriately submitted for payment.” OIG is conducting a national review of kwashiorkor because the diagnosis is rare in the United States and continues to issue reports with similar conclusions (RMC 9/21/15, p. 8). View the report at http://go.usa.gov/cyBAd.

◆ Medicare overpaid hospitals $6.3 million for inpatient stem cell transplant procedures that could be provided in outpatient settings, OIG says in a new report (A-09-14-02037). OIG reviewed 143 inpatient claims for stem cell transplants submitted from January 2010 through September 2013. Stem cell transplants are not on the inpatient-only list and are routinely done on outpatients. If they are performed on inpatients, they fall under four MS-DRGs that have 10- to 21-day lengths of stay. OIG’s findings: 133 claims that had lengths of stay of one to two days did not comply with Medicare requirements. For 120 of these claims, the stays should have been billed as outpatient services or outpatient with observation. “These claims did not have clinical evidence supporting that an inpatient level of care was required before, during, or after the transplant procedures were performed,” OIG contends. The other 13 claims had the wrong MS-DRGs. Visit http://go.usa.gov/cyVpw.
If You Don’t Already Subscribe to the Newsletter, Here Are Three Easy Ways to Sign Up:

1. Return to any Web page that linked you to this issue

2. Go to the MarketPlace at www.AISHealth.com and click on “Newsletters.”

3. Call Customer Service at 800-521-4323

If you are a subscriber and want to provide regular access to the newsletter — and other subscriber-only resources at AISHealth.com — to others in your organization:

Call Customer Service at 800-521-4323 to discuss AIS’s very reasonable rates for your on-site distribution of each issue. (Please don’t forward these PDF editions without prior authorization from AIS, since strict copyright restrictions apply.)