Proposed OPPS Rule Slashes Payments for 340B Drugs, Some Provider-Based Departments

Hospitals got a body blow in the proposed 2018 outpatient prospective payment system (OPPS) regulation published in the July 20 Federal Register, and provider-based space is the target, again.

CMS is floating a plan to slash payments under the 340B drug-discount program from average sales price (ASP) plus 6% to ASP minus 22.5%. At hospitals, only outpatient areas, such as provider-based departments, are eligible for 340B discounts. On top of that, CMS would cut payments in half to off-campus provider-based space established after Nov. 2, 2015, from 50% of the OPPS payment to 25%. The cut flows from Sec. 603 of the 2015 Bipartisan Budget Act, which put an end to OPPS billing by the newer off-campus provider-based departments, which CMS recently dubbed “non-excepted departments.” CMS had to develop a different way to pay for non-excepted services that didn’t involve OPPS, and CMS has more fully articulated it in the 2018 proposed Medicare physician fee schedule regulation unveiled at the same time as the OPPS rule.

Together, the proposals give some compliance experts the feeling that CMS is pushing provider-based space off the cliff.

“I think CMS wants hospitals to divest these departments as soon as possible,” says Valerie Rinkle, president of Valorize Consulting. “This could be part of a strategy to get hospitals to make provider-based departments freestanding ambulatory surgery centers or clinics.” That conclusion also seems inescapable to Boston attorney Larry Vernaglia, with Foley & Lardner LLP. “50% was rough, but 25% is almost designed to strangle those babies in their cribs,” Vernaglia says. “CMS will keep cutting until outpatient provider-based departments are not viable anymore.”

In Largest EMTALA CMP Case, Patients Stayed in ED Although Hospital Had Psych Unit

Even though AnMed Health in South Carolina had on-call psychiatrists and inpatient mental health units in its hospitals, they allegedly kept some psychiatric patients in their emergency rooms, sometimes for days or weeks at a time, without properly evaluating and/or treating them in violation of the Emergency Medical Treatment and Labor Act (EMTALA), according to the HHS Office of Inspector General. As a result, AnMed Health has agreed to pay $1.295 million to settle a civil monetary penalty (CMP) law case.

That’s the largest CMP settlement ever for alleged EMTALA violations.

AnMed had a policy of handling emergency psychiatric patients differently depending on whether they were voluntarily or involuntarily committed for mental health treatment and had money, the settlement states. “The idea that voluntary vs. involuntary would be the trigger by which patients would get access...”

continued on p. 4
is extraordinary,” OIG Senior Counsel Sandra Sands tells RMC. “How is it they developed this policy and why the policy persisted as long as it did I found very surprising.”

EMTALA requires hospitals to give “medical screening exams” to all patients who show up in the emergency room regardless of ability to pay and to stabilize them if they have “emergency medical conditions.” Patients may be transferred when hospitals lack the capacity to treat them, and receiving hospitals must accept transfers if they have the capacity to treat the patients.

According to the settlement, OIG’s investigation identified 36 “incidents” of an alleged EMTALA violation. People showed up at the emergency department (ED) with unstable psychiatric emergency medical conditions. “Instead of being examined and treated by on-call psychiatrists, patients were involuntarily committed, treated by ED physicians and kept in AnMed’s ED for days or weeks instead of being admitted to AnMed’s psychiatric unit for stabilizing treatment,” OIG alleged in the settlement. Three of the incidents were described in the settlement:

◆ Law enforcement brought in a 32-year-old woman with psychosis and homicidal ideation in 2012. She wasn’t given a psych exam, treated by available psychiatrists or admitted to the psych unit, the settlement said. Instead, the woman spent 38 days in the ED, and at some point a psychiatrist from another facility who was familiar with her condition saw her and prescribed various drugs for her condition. After eventually reaching her “baseline,” the woman was decertified and discharged home.

◆ A 62-year-old woman was brought to the AnMed ED in 2012 by a detention officer. She had brandished a knife on family members and suffered “acute psychosocial issues.” Although the woman was examined by an ED physician, no on-call psychiatrists examined or treated her. She remained in the ED for 20 days before transferring to another facility.

◆ The same year, a 55-year-old catatonic woman presented to AnMed’s ED with a history of schizophrenia. AnAnMed ED physician screened the patient (e.g., performed a CT scan of the brain and blood work). The patient spent seven days in the ED. It’s unclear whether she was evaluated or treated by an on-call psychiatrist.

There were a couple dozen patients like this, and most were suicidal and/or homicidal and had depression, schizophrenia, bipolar disorder, drug abuse, psychosis, personality disorders and major serious mental illnesses, the settlement contends. “AnMed’s policies provided that if an individual should be involuntarily committed and did not have financial resources, the attending physician could write an order for the local mental health center to evaluate the patient for commitment to the state mental health system after the patient is medically stable,” according to the settlement.

The main question is whether AnMed met its EMTALA obligation to patients to screen and stabilize them, Sands explains. “Our experts concluded the answer was no because the hospitals did not avail these patients of on-call psychiatrists and inpatient facilities,” she says.

EMTALA Fines Have Increased

When Sands has dealt with the intersection of EMTALA and psychiatric patients before, “it has been because hospitals didn’t have the capability to treat and have not been able to get access to hospitals that have the capability to treat and were trying to effectuate appropriate transfers.” That wasn’t the case here.

The AnMed settlement is one of a several recent EMTALA cases involving psychiatric patients. For example, last year, Floyd Medical Center in Rome, Ga., agreed to accept the transfer of a psychiatric patient, and yet the hospital wound up paying $50,000 to settle a CMP case over an alleged EMTALA violation. Things went south when the patient arrived for
involuntary commitment; he became agitated, and there was a scuffle with security guards, according to the settlement. The hospital never contacted its on-call psychiatrist, and ultimately the patient, who was injured in the process, got carted off to jail (RMC 3/28/16, p. 1).

“In the past year or two, psychiatric patients and transfers have been the biggest EMTALA concern,” says Austin, Tex., attorney Kathy Poppitt, with King & Spalding. “Hospitals are getting that, but I’m not sure there is consistency on this issue.”

With the scourge of opiate addiction and the shortage of inpatient psychiatric beds, hospitals should keep reviewing and updating their ED treatment of psychiatric patients, Poppitt says. “There can be an increase in the number of psych patients coming to the ED as well as their severity,” she notes. “A big red flag” for hospitals under EMTALA is boarding patients with psychiatric emergencies in the ED for significant periods of time, Poppitt says. “You need to look at your systems and see what can be improved.” If hospitals lack inpatient psych units, make sure you “pull out all the stops to find appropriate places for them.” It’s worse to board patients in the ED if there are empty psych beds in your own facility, Poppitt says.

Hospitals face higher EMTALA fines now, although this didn’t affect AnMed because its alleged violations occurred before the increase. Because EMTALA per-incident fines were increased as required by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, hospitals with more than 100 beds now will be fined a maximum of $103,139 for each violation, up from $50,000.

AnMed’s attorney did not respond to RMC’s requests for comment. AnMed Health did not admit to liability in the settlement.

Contact Poppitt at kpoppitt@kslaw.com. ◆

Audits of IMM Look at Timing of Discharge Appeal Notices

Sometimes, hospitals are audited when there’s too little of something rather than too much of it.

That was the case with a recent audit of compliance with the Important Message from Medicare (IMM). Livanta, a quality improvement organization (QIO), has been reviewing the use of IMMs at 12 hospitals owned by Dignity Health, a California-based health system.

“We were told one of the reasons why the QIO audited some of our facilities was they saw a decrease in discharge disputes,” says Gail Moxley, program manager of care coordination.

CMS requires hospitals to give inpatients the IMM to explain their right to appeal discharges. The IMM must be delivered to all Medicare patients twice. The first time, patients receive it at admission, and the second time, patients must get a copy two days before discharge, as a reminder of their appeal rights. For example, if patients stay in the hospital four days, they will receive the IMM two days into their stay, Moxley says. “That provides the patient time to dispute the discharge,” she says.

Hospitals must use the CMS version of the IMM. “You’re not allowed to customize it,” she notes.

At Dignity hospitals, patients are given the first IMM at registration, with all their other forms. The subsequent copy comes from care coordination. If patients have a shorter stay, perhaps two days or even less if they recover faster than expected under the two-midnight rule, and they wind up receiving the second IMM a day or less before discharge, the hospital gives patients four hours to file an appeal before effectuating the discharge. “They have to have time to appeal the discharge,” Moxley notes. “If we give them the IMM at noon on the day of discharge, we can’t discharge that patient before 4 p.m.” Appeals are filed with QIOs.

Livanta began audits at Dignity in May and June. The reviews are not in person; QIOs ask hospitals to send copies of IMMs. “What they are auditing is whether we gave IMMs at the time of admission, whether patients signed them and whether we gave them a second IMM a day or less before discharge, the hospital gives patients four hours to file an appeal before effectuating the discharge. “They have to have time to appeal the discharge,” Moxley notes. “If we give them the IMM at noon on the day of discharge, we can’t discharge that patient before 4 p.m.” Appeals are filed with QIOs.

Five Notices Are Reviewed

For example, when patients don’t sign the IMM because they’re not competent, the hospital has to locate a family member to sign. In these reviews, the QIO may ask about that. The QIO may also question the hospital about who signed the IMM if it can’t read the handwriting. Moxley notes that few patients appeal their discharges, but compliance with the IMM is taken seriously, as it is with the other types of beneficiary notices. There are four more:

◆ The Medicare Outpatient Observation Notice (MOON), which is the new kid on the block (RMC 5/8/17, p. 1; 12/12/16, p. 1);
◆ The Advance Beneficiary Notice (ABN), which requires patients to take financial responsibility for outpatient services that Medicare considers medically unnecessary and therefore not covered;

◆ The Hospital-Issued Notice of Non-Coverage (HINN), which asks patients to accept financial responsibility for an inpatient stay that Medicare considers medically unnecessary (e.g., a social admission); and

◆ The Detailed Notice of Discharge (DND), which patients receive after they decide to appeal their discharges. Noncompliance with beneficiary notices can put a hospital’s provider status in jeopardy under the Medicare conditions of participation. Several of these notices have recently been updated, effective 60 days from 2017, according to the CMS website.

Dignity Health ensures its forms are always current by linking its operations manual directly to the website, Moxley says. Registrars and care coordinators also use work flows that take the guesswork out of it (see box, p. 5). “No one deviates from the work flows,” she says. “Once they know it, it’s pretty simple.”

Keep an Eye on EHRs

Now and then, an IMM or other form falls through the cracks. It’s because an employee forgot to give it to the patient or a process needs improving. “There are a lot of patients in some facilities that we have to provide these forms,” Moxley notes. “We review these forms annually with staff to make sure they understand it.” That includes patient choice forms—the forms patients are given to ensure they know they can select any post-acute care provider (e.g., home health) and are not obliged to select providers that the hospital owns or is affiliated with or prefers to work with.

The internal reviews are seen as an opportunity to identify potential process improvements, Moxley notes. One problem that Dignity Health identified and rectified: IMMs and other beneficiary notification forms were scanned into the computer system but not into the electronic health records (EHRs), so they were living in separate systems. “We had to make sure we were integrated into the actual EHR system,” she says. That way, when Dignity is audited, “we can go to one area and find all of them.”

Meanwhile, Dignity is awaiting results of the Livanta IMM review.

Contact Moxley at gail.moxley@dignityhealth.org. View the beneficiary notices at http://tinyurl.com/yacw6h4e.

OPPS Rule Would Slash Payments

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The proposed 340B payment cut is a monumental change. In making this move, CMS could be violating the statute that created the 340B program, which requires pharmaceutical manufacturers to discount drugs to “covered entities,” including critical access hospitals, sole community hospitals, disproportionate share hospitals, freestanding cancer hospitals, children’s hospitals, rural referral centers and hemophilia clinics, says Washington, D.C., attorney Andy Ruskin, with Morgan Lewis. “What CMS is trying to do here is get money from manufacturers that Congress in the 340B statute clearly wanted the covered entities to have to fulfill their mission,” he says. “CMS is essentially giving itself a rebate from manufacturers.”

Even non-340B hospitals are being dragged into the drama, Rinkle says. The OPPS regulation would require them to use a new modifier to identify drugs not purchased under the 340B program. “It’s the most crazy thing,” Rinkle says. “CMS makes it sound like the payment cut is automatic unless the modifier is there.” So while the Trump administration says it wants to reduce administrative burden, “it seems to be putting an administrative burden on hospitals that get no benefit from 340B” (e.g., hospitals that are not eligible for the 340B drug-discount program because they are for-profits), she explains.

Why CMS Proposed the 340B Cut

CMS explained its reasoning for the 340B payment cut. The change in payment methodology would better reflect “the resources and acquisition costs that these hospitals incur,” according to the proposed regulation. Hospitals enjoy drug discounts ranging from 20% to 50% because of the 340B program, and their utilization has grown, CMS said, citing a Government Accountability Office (GAO) report. For example, the Medicare Payment Advisory Commission (MedPAC) found that Part B spending on chemotherapy drugs and drug administration grew faster between 2008 and 2012 at 340B hospitals than non-340B hospitals. That means higher copays for Medicare patients, the regulation noted.

The bottom line is, more hospitals are participating in 340B—from 583 in 2005 to 2,140 in 2014—and they’re saving billions of dollars on drugs as a result. That’s why it’s time to revisit the 340B pricing methodology under OPPS, especially “because of the inextricable link of the Medicare payment rate to the beneficiary cost-sharing amount,” CMS stated.
Decisions, Decisions: Is the Important Message From Medicare Required?

This decision tree may help hospitals determine whether they have to deliver the Important Message from Medicare (IMM) to patients. The IMM informs patients of their right to appeal discharges. The decision tree was developed by Dignity Health. Contact Gail Moxley, program manager of care coordination, at gail.moxley@dignityhealth.org.

Patient Notification – Important Message from Medicare (IMM)

(ALL MEDICARE BENEFICIARIES – INCLUDING FFS, ADVANTAGE, MEDICARE SECONDARY)

- Is the Physician Order status In-Patient or Observation?
  - Yes
    - Is this a Medicare Patient?
      - Yes
        - Stop Does Not Apply
      - No
        - Patient Access
          - Will provide the patient with the original IMM at time of admission or within 2 days of admission.
          - Obtain Patient/family signature on document.
          - If patient/family refuses to sign, document refusal on letter.
          - Provide copy of signed IMM to patient/family.
          - The original signed IMM will be sent to the electronic medical record.
  - No
    - Does the Physician Order status change to In-Patient?
      - Yes
        - Stop Does Not Apply
      - No
        - Patient Notification – Important Message from Medicare (IMM)
          - IP
            - Does the Physician Order status change to In-Patient?
              - Yes
                - Patient Notification – Important Message from Medicare (IMM)
                  - OBS
                    - Does the Physician Order status change to In-Patient?
                      - Yes
                        - Stop Does Not Apply
                      - No
                        - Patient Access
                          - Will provide the patient with the original IMM at time of admission or within 2 days of admission.
                          - Obtain Patient/family signature on document.
                          - If patient/family refuses to sign, document refusal on letter.
                          - Provide copy of signed IMM to patient/family.
                          - The original signed IMM will be sent to the electronic medical record.
          - No
            - Care Coordination
              - Anticipated Discharge
                - Within 2 days of discharge, CC will deliver a copy of the IMM to the patient.
                - Obtain Patient/family signature on document.
                - If someone other than the patient signs; the RN Care Coordinator’s name, the representative’s name and method of contact must be documented on the IMM.
                - If contacted via phone, also document the phone number and send completed hard copy via certified mail, return receipt requested or any other method that can provide a signed verification of delivery [signed verification must be placed in patient chart]. A fax/email copy can be provided if requested by representative but must meet HIPAA requirements [sent secure if emailed]
                - If patient is unable to sign / refuses to sign and there is no representative, document the refusal or reason unable to sign, certification of the delivery, name, title and signature of RN Care Coordinator, date & time notice was presented to patient in the additional information section.
                - CC will document in Cerner Discharge Plan form that a copy of the IMM was issued.
              - Day of Discharge
                - CC will confirm delivery of IMM to patient within the last 2 days.
                - If the IMM was not delivered within the last 2 days, the CC will deliver a copy of the IMM to the patient.
                - CC must give patient 4 hours to consider their right to request a QIO review.
                - Obtain Patient/family signature on document.
                - If someone other than the patient signs; the RN Care Coordinator’s name, the representative’s name and method of contact must be documented on the IMM.
                - If contacted via phone, also document the phone number and send completed hard copy via certified mail, return receipt requested or any other method that can provide a signed verification of delivery [signed verification must be placed in patient chart]. A fax/email copy can be provided if requested by representative but must meet HIPAA requirements [sent secure if emailed]
                - If patient is unable to sign / refuses to sign and there is no representative, document the refusal or reason unable to sign, certification of the delivery, name, title and signature of RN Care Coordinator, date & time notice was presented to patient in the additional information section.
                - CC will document in Cerner Discharge Plan form that a copy of the IMM was issued.
To carry out this change, CMS needs more information about drugs that are purchased under the 340B program vs. drugs that aren’t. To make this distinction, hospitals that don’t get the discount must use a new modifier starting Jan. 1, assuming CMS sticks to its guns in the final rule. More modifier details will be forthcoming there and in subregulatory guidance.

**Sometimes Smoke Is Just Smoke**

CMS is jumping to the conclusion that the 340B discounts lead to overutilization, Ruskin says. “They are reading shifts in utilization as ‘where there’s smoke, there’s fire,’” he says. “Sometimes smoke is just smoke.” There are better ways to address potential overutilization, such as edits, he says. “Cutting payments to safety-net hospitals is not the answer.”

The payment reduction “undercuts the purpose and intent of the 340B program, which allows covered entities to stretch their resources further,” says Los Angeles attorney Anil Shankar, with Foley & Lardner LLP. “If other payers follow suit and reduce payments to 340B covered entities, the benefit of being 340B will disappear.” The cut did not come completely out of the blue, however, because MedPAC mentioned this before as a way to save money, although it didn’t go this far, Shankar says. “There are a lot of voices criticizing the 340B program as having grown too much,” but that was by design under the Affordable Care Act, he notes.

If the cuts are finalized, some hospitals may ditch the 340B program, says Karolyn Woo-Miles, a principal at Deloitte & Touche in Costa Mesa, Calif. “The attractiveness of 340B may be lessened but the compliance expectations are the same,” she notes. Covered entities have to satisfy definitions of “eligible patients” and “covered outpatient drugs,” for example.

**340B Audits Are Still Ramping Up**

Meanwhile, audits of compliance with 340B requirements have been on the upswing, with hospitals repaying drug manufacturers if they make mistakes, including duplicate discounts and diversion (RMC 10/24/16, p. 1). The exacting audits are conducted by the HHS Health Resources and Service Administration, which oversees the 340B program, and the budgets for audits keep climbing, Woo-Miles notes. “There are various pressures,” she says. “HRSA audits are in response to Congress, the GAO and others asking for more transparency about 340B because they are thinking hospitals are getting all these benefits from the program without passing them on to their patients.” But she is a bit mystified CMS is targeting 340B; “in the grand scheme of things, it’s a small part of overall drug spending.”

There’s a question of whether it will be worthwhile to stay in the 340B program going forward in a world of ASP minus 22.5%, Woo-Miles says. “For smaller disproportionate share hospitals that only get a few million, is it worth the time, with all the scrutiny? For some of the larger hospitals that get $20 million, it probably would be worth staying in,” she says.

While all this shakes out, compliance officers shouldn’t take their eye off the 340B ball. But they may have a harder time getting resources to oversee 340B if the cuts go through. “It just makes it a harder sell,” Woo-Miles notes. “You’re not getting the same return on investment.”

**More Cuts for Newer Provider-Based Space**

As for the other half of the double whammy, the payment reduction for off-campus provider-based space moved from the proposed OPPS rule to the proposed 2018 Medicare physician fee schedule regulation, which was published in the July 21 Federal Register. The cuts stem from Sec. 603 of the Bipartisan Budget Act of 2015, where Congress said goodbye to OPPS billing by off-campus provider-based space created after Nov. 2, 2015, with some exceptions (RMC 11/23/15, p. 1; 11/2/15, p. 1). Provider-based departments that were billing the OPPS up to that date are excepted, so they’re safe to bill the OPPS. But if they opened for business after that, non-excepted departments have to shop for a new payment system—unless they were in the middle of construction at the time Sec. 603 took effect or are cancer hospitals, two concessions Congress made later in the 21st Century Cures Act (RMC 12/5/16, p. 3).

The driver behind Sec. 603 is the fact that Medicare pays more for the same services when they’re performed in provider-based space—a facility fee and a physician fee—compared to freestanding clinics. But CMS still had to have a way to pay hospitals for non-excepted services at non-excepted departments. Just because they weren’t grandfathered in didn’t mean hospitals were going to convert their provider-based departments to ambulatory surgery centers (ASCs) or freestanding clinics, mostly because provider-based space is eligible for 340B drug discounts. At first CMS terrified the industry with a payment method in the proposed 2017 OPPS rule that would have left hospitals at the mercy of physicians, but after an outcry, CMS came up with something more manageable in the 2017 final rule. It set forth new rates for non-excepted items and services under the Medicare physician fee schedule. While it’s only
50% of the OPPS amount, hospitals with non-exceptioned provider-based departments are able to stick with their UB-04 claim forms. Costs and charges can flow through their cost reports, and hospitals are able to report them on Medicare provider statistical and reimbursement reports. That’s where things stand, although CMS cautioned it was transitional.

**Only One Code Was Used**

Now the 2018 proposed rule would slash the 50% to 25% of the OPPS payment. CMS dubs it the physician fee schedule “relativity adjuster.”

As CMS explains in the Medicare physician fee schedule regulation, it arrived at the 25% rate for non-exceptioned off-campus provider-based departments by comparing the codes for the service most commonly billed in the off-campus provider-based department. That turned out to be the sole outpatient hospital clinic visit HCPCS code (G0463). “This proposed 25 percent PFS Relativity Adjuster is based solely on the comparison for the visit services that reflect greater than 50 percent of services billed in off-campus [provider-based departments],” the proposed rule stated. CMS acknowledged the methodology may not be flawless, but it worked with the data it has for now.

It seems a possible violation of the Administrative Procedures Act (APA) to shift the non-exceptioned provider-based payment method to the Medicare physician fee schedule regulation without responding to industry comments submitted to the 2017 OPPS interim final rule about the relativity adjustment factor calculation of 50%, Rinkle says. CMS got a lot of comments about “how to make it more appropriate,” but they were just blown off, she says. CMS shifted gears to the physician fee schedule and HCPCS G0463 as a vehicle to make further payment cuts, Rinkle says. “I would argue they can’t do this,” Ruskin says. “They are making all comments moot.” Hospitals could seek redress in federal court for violating the APA, he notes.

**Where Hospitals Will Go From Here**

If CMS sticks to the payment cuts, hospitals will have few options, Vernaglia says. They can close non-exceptioned provider-based departments, convert them to a model that would still be eligible for OPPS reimbursement (e.g., an urgent/emergency medicine or partial inpatient strategy), move them on campus in space they now use for administration or cost shift to private insurers, he says.

But the “sky is not necessarily falling,” Rinkle says. Hospitals may be able to move off-campus non-exceptioned departments on-campus where non-clinical space freed up and where the payment changes have no currency, or they can convert to ASCs or free-standing clinics in a manner that mitigates the financial impact.

Vernaglia and other compliance experts urge hospitals to contact CMS and their members of Congress to try to modify the proposals.

Contact Vernaglia at lvernaglia@foley.com, Ruskin at aruskin@morganlewis.com, Rinkle at valerie.rinkle@valorizeconsulting.com, Woo-Miles at kwoo@deloitte.com and Shankar at ashankar@foley.com. View the OPPS proposed rule at http://tinyurl.com/y6vlzrj5 and the proposed physician fee schedule at http://tinyurl.com/yahfwwp.

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**CMS Transmittals and Federal Register Regulations**

**July 7 - 20**

Live links to the following documents are included on RMC’s subscriber-only webpage at www.hcca-info.org. Please click on “CMS Transmittals and Regulations.”

**Transmittals**

(R) indicates a replacement transmittal.

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

- Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS), Trans. 3805 (July 11, 2017)
- Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS), Trans. 199 (July 11, 2017)

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

- Clarifying the Instructions for Amending or Correcting Entries in Medical Records, Trans. 732 (July 21, 2017)

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

- Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS), Trans. 199 (July 11, 2017)

**Pub. 100-22, Medicare Quality Reporting Incentive Programs**

- Fiscal Year 2018 and After Payments to Skilled Nursing Facilities That Do Not Submit Required Quality Data, Trans. 67 (July 14, 2017)

**Federal Register**

**Final Regulations**

- Medicare and Medicaid Programs; Conditions of Participation for Home Health Agencies; Delay of Effective Date, 82 Fed. Reg. 31729 (July 10, 2017)
- Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities, 82 Fed. Reg. 32256 (July 13, 2017)

**Proposed Regulation**

- Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 33558 (July 20, 2017)
**NEWS BRIEFS**

- An Ohio management company, a therapy company, a hospice provider and two executives have agreed to pay $19.5 million to settle false claims allegations over medically unnecessary therapy and hospice services, the Department of Justice said July 17. Foundations Health Solutions Inc. (FHS) provided management services to skilled nursing facilities (SNFs), while Olympia Therapy Inc. performed rehab on patients at the SNFs managed by FHS, which is the corporate successor to Provider Services Inc. (PSI). PSI merged into BCFL Holdings Inc. (BCFL) in 2010 and was renamed FHS in 2013. Tridia Hospice Care Inc. was the other company, and Brian Colleran and Daniel Parker partially controlled or owned PSI, BCFL, FHS, Olympia, and Tridia between 2008 and 2013. According to DOJ, Olympia and PSI/BCFL allegedly billed Medicare for medically unnecessary therapy at 18 SNFs between January 2008 and December 2012. Also, Tridia allegedly submitted false claims for hospice patients who weren’t eligible for the services because the hospice didn’t perform appropriate certifications or medical exams, DOJ said. The settlement includes a five-year corporate integrity agreement with the HHS Office of Inspector General for FHS and Colleran. The false claims settlement was set in motion by whistleblowers in two separate lawsuits. They are Vladimir Trakhter, a former Olympia employee, and Paula Bourne and La’Tasha Goodwin, former Tridia employees. Visit http://tinyurl.com/ya3np4p5.

- Critical access hospitals and small rural hospitals with 100 or fewer beds would be spared the direct physician supervision requirement for outpatient therapeutic services for two years, according to a provision in the proposed 2018 outpatient prospective payment system (OPPS) regulation. If it’s finalized, there would be a two-year moratorium (in 2018 and 2019). The OPPS rule appeared in the July 20 Federal Register. Visit http://tinyurl.com/y6vlzrj5.

- The proposed 2018 OPPS regulation would remove knee replacement from the inpatient-only list, and CMS is asking hospitals for comment on whether to do the same for hip replacement. That means CMS would end its policy of only paying for knee arthroplasty if it were performed on an inpatient basis. Hospitals are reimbursed far less for joint replacements under the OPPS than DRGs. Visit http://tinyurl.com/y6vlzrj5.

- The HHS Office of Inspector General has released the monthly update to its Work Plan. New items include audits of high-risk, error-prone home health agencies and “Part B payments for ambulance services subject to Part A skilled nursing facility consolidated billing requirements.” Visit https://go.usa.gov/xNSuY.

- The U.S. Attorney’s Office for the Northern District of Illinois said July 18 it has created a new unit dedicated to prosecuting criminal health fraud. It will be staffed by five prosecutors. “The unit will be tasked with prosecuting defendants in all types of health care fraud, from providers who engage in fraudulent billing schemes to doctors who falsify patients’ diagnoses to justify expensive tests or procedures that aren’t medically necessary,” the U.S. attorney’s office stated. Visit http://tinyurl.com/y7wof4jq.

- In a national fraud “takedown,” the Department of Justice and HHS said July 13 it charged 412 people, including 115 physicians, nurses and other licensed medical professionals, in connection with health fraud schemes. This was the largest health fraud enforcement action ever by the Medicare strike forces, DOJ said. HHS also began suspension actions against 295 providers. The enforcement action focused partly on Medicare, Medicaid, and TRICARE billing schemes around medically unnecessary prescription drugs and compounded medications that often weren’t bought and/or distributed to patients, DOJ said. “The charges also involve individuals contributing to the opioid epidemic, with a particular focus on medical professionals involved in the unlawful distribution of opioids and other prescription narcotics, a particular focus for the Department,” according to DOJ. Takedowns occurred in various cities. In southern Florida, 77 people were charged in connection with false claims for services, including home health care, mental health services and pharmacy fraud. For example, the owner of a "purported addiction treatment center and home for recovering addicts and one other individual were charged in a scheme involving the submission of over $58 million in fraudulent medical insurance claims for purported drug treatment services. The allegations include actively recruiting addicted patients to move to South Florida so that the co-conspirators could bill insurance companies for fraudulent treatment and testing, in return for which, the co-conspirators offered kickbacks to patients in the form of gift cards, free airline travel, trips to casinos and strip clubs, and drugs,” DOJ said. Visit http://tinyurl.com/yacx8qbs.