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IN THIS ISSUE

Price Transparency: 2 of 3 Hospitals Not Complying with New CMS Disclosure Rules, Study Finds

Despite vociferous industry protest, the Centers for Medicare and Medicaid Services' (CMS's) controversial new hospital price transparency rule officially took effect on Jan. 1, 2021. But through mid-March, nearly 2 out of 3 hospitals aren't actually complying with it. At least, that's the conclusion of a study published by the journal HealthAffairs on March 16.

The Hospital Price Transparency Rule

Section 2718(e) of the Public Health Service Act, which is part of the Affordable Care Act (ACA), requires "[e]ach hospital" to make public and annually update "a list of the hospital's standard charges for items and services provided by the hospital" (in accordance with guidelines developed by CMS. During the initial years after the ACA took effect, hospitals complied with this requirement by publishing their chargemasters in accordance with CMS guidance.

After initially going along with this approach, CMS became "concerned" that chargemasters "are not helpful to patients

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Compliance Perspectives: Medicare Medical Necessity Denials and How Your Lab Can Prevent Them

Ensuring that the lab services you bill for meet Medicare medical necessity requirements is one of the oldest challenges faced by lab compliance managers. And it doesn't get any easier over time. The complication stems from the simple fact that, in most cases, labs perform but don't order the services they bill for; those services are ordered by an unrelated physician. This creates an inherent tension between the sides to the extent that labs rely on ordering physicians to

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for determining what they are likely to pay for a particular service or hospital stay." As the agency pointed out, chargemaster rates tend to be "highly inflated" and "bear little relationship to market rates" because they list non-discounted, fee-for-service prices. And without meaningful price information, consumers would not be able to make informed price decisions and exert downward pressure on health care costs the way the ACA envisioned.

So, in August 2019, CMS adopted a new policy by issuing a notice of proposed rulemaking dramatically expanding the amount of information that hospitals would have to make public under Section 2718(e). In November 2019, CMS published the final rule, aka, "Price Transparency Requirements for Hospitals to Make Standard Charges Public" requiring hospitals to make public "a machine-readable file containing a list of all standard charges for all items and services." The rule defined "standard charges" as including:

- Gross charges, or the non-discounted rate, as reflected in a hospital's chargemaster;
- Discounted cash prices, or the rate the hospital would charge individuals who pay cash;
- Payer-specific negotiated charges, or the rate the hospital negotiated with an insurer or other third-party payor (for example, an insurer) for a particular item or service provided in the hospital;
- De-identified minimum negotiated rates, or the lowest rates that a hospital negotiated with all third-party payors, without identifying those payors; and
- De-identified maximum negotiated rates, or the highest rates that a hospital negotiated with all third-party payors, without identifying the payors.

Hospitals that fail to comply face civil penalties of up to $300 per hospital per day or $109,500 per year. CMS has also reserved the right to re-visit and increase the civil penalty amounts.

The Hospital Industry Pushes Back

To say that the final rule didn't go over well with the hospital industry would be a bit of an understatement. In addition to imposing onerous new administrative burdens, hospitals complained that the final rule would force them to disclose important proprietary information and potentially endanger their relationships with patients. The final rule was originally slated to take effect on 2020 but CMS pushed back the start date by one year to Jan. 1, 2021.

The American Hospital Association (AHA) challenged the law in federal court and appealed to the U.S. Court of Appeals for the District of Columbia Circuit after the district court ruled against them. But the appeal

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failed when the D.C. Appeals Court affirmed the lower court's decision in December 2020, paving the way for the rule to take effect on Jan. 1, 2021 even though the industry insisted hospitals needed more time to get their price disclosure systems up and running.

The Price Transparency Compliance Study

Given the relatively low penalties and hospitals' protests about not being ready, it makes a lot of sense to determine whether the price transparency rule is actually being followed. To answer that question, the authors of the HealthAffairs study compiled the price transparency files of the 100 largest hospitals in the U.S. by bed count over the period from late January 2021 through early February 2021. Using Google to search for the hospitals' standard charges, the authors downloaded and saved the data files using the name of each file as posted. The authors then opened each individual data file and checked:

- Whether the data set contained all the variables necessary to be compliant; and
- Whether these variables complied with all necessary requirements: For example, payer-specific negotiated charges needed to "be clearly associated with the name of the third-party payor and plan."

If files did not contain required variables, or cover all items and services, the hospitals were recorded as being unambiguously noncompliant. To err on the side of caution, hospitals didn't get the unambiguously noncompliant label if there was any question or case to be made showing that the hospital was in compliance.

The Study Findings

Of the 100 hospitals in the sample, 65 were labeled unambiguously noncompliant. Among these 65:

- 12, or 18 percent, didn't post any files or provided links to searchable databases that weren't downloadable; and
- 53, or 82 percent, either didn't include the payor-specific negotiated rates with the name of the payor and plan clearly associated with the charges or were noncompliant in some other way.

Of the remaining 35 hospitals that didn't get the unambiguously noncompliant label, at least 22 appeared to be compliant, and 13 hospitals clearly exceeded the regulations in terms of the amount of information disclosed. Examples:

The file for Massachusetts General Hospital contained 3,669,193 observations covering more than 65,000 items and services for 19 payors and 54 plans (with 54 unique payor-plan-contract combinations), as well as data on inpatient and outpatient contracting details; and

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- The file for Riverside Methodist Hospital of Ohio contained data for more than 120 payor-plan combinations covering more than 98,000 items and services (inpatient, outpatient, pharmacy, professional and supplies).

Takeaway

There are some important caveats to keep in mind. First and foremost, we are still very, very early into the new transparency regime. These initial returns reflect not defiance but administrative and technology challenges that confirm industry contentions that hospitals simply weren't yet set up to comply with the rule by the Jan. 1 start date.

The other reason for not making too much about the study, which the authors readily acknowledge, are the challenges to assessing compliance. Thus, for example, the authors noted the difficulties in ascertaining whether the files contained "all items and services, including individual items and services and service packages, that could be provided by a hospital to a patient in connection with an impatient admission or an outpatient department visit for which the hospital has established a standard charge." The researchers also stated that it was also difficult to ascertain if a hospital's file contains payor-specific negotiated charges for all payors and plans.

Labs IN COURT

A roundup of recent cases and enforcement actions involving the diagnostics industry

Theranos Redux? Feds Target New Silicon Valley Diagnostics Start-Up Investment Scam

Case: Federal prosecutors have filed criminal charges against the co-founders of a San Francisco biotechnology start-up firm with defrauding investors by making bloated claims about a revolutionary diagnostics product. No, it's not Theranos, but uBiome Inc, a business created in 2012 to develop and commercialize tests to detect microbiomes in the gut and other parts of the body. uBiome's Gut Explorer, Smart Gut and SmartJane were sold in mail order kits that patients could use to collect samples from home, complete surveys and get results online in a few weeks. According to prosecutors, uBiome's co-founders Zachary Apte and Jessica Richman were able to raise over $76 million in a pair of fundraising rounds by misleading investors about the firm's revenue growth and ability to secure coverage from payors even though many tests weren't clinically validated or medically necessary. uBiome filed for bankruptcy in 2019.

Significance: Acting U.S. Attorney Stephanie Hinds is in charge of the criminal prosecution. If the name sounds familiar, it may be because Ms. Hinds' office is also prosecuting Elizabeth Holmes and Theranos. "The

innovation that emerges from our Bay Area companies is unparalleled," noted Ms. Hinds, "but all innovation must exist within the boundaries of the law." In addition to the criminal charges, Apte and Richman have been hit with civil charges of stock fraud from the Securities Exchange Commission (SEC).

Florida Court Upholds Conviction of Physician at Center of Massive Drug Test Scam

Case: In February 2019, the physician/medical director of a pair of sober home clinics in clinics was sentenced to 11 years in prison and ordered to pay $1 million in restitution for his role in a massive fraud scheme involving billings for millions of dollars of unnecessary urine drug tests on recovering addicts. I was just a patsy in the 20-member conspiracy, the physician had claimed. But after an 8-day trial, the Florida federal jury found him guilty of conspiracy to commit health care fraud and distribute controlled substances, as well as seven counts of unlawfully dispensing controlled substances. The owner of the clinics who served as ringleader of the scheme is also serving a 27-year sentence after being convicted of multiple charges.

Significance: The U.S. Court of Appeals for the 11th Circuit ruled that there was more than enough evidence to support the verdict and sentence and tossed the appeal. The physician played a central role in the scam. It wasn't just that he ordered all of the tests but also the way he ordered them. For one lab, he issued a standing order authorizing as medically necessary 2 to 3 scheduled and up to 2 random tests on a single patient per week. For the second lab, he pre-signed blank requisition forms for drug tests leaving the patient information blank so that others could enter it later. In each case, staff photocopied the documents and used them to maximum advantage, often ordering tests and providing their own urine samples for patients who didn't show up for appointments [*U.S. v. Abovyan*, 2021 U.S. App. LEXIS 5030, 988 F.3d 1288, 28 Fla. L. Weekly Fed. C 2452].

Michigan Cardiologist Shells Out $2 Million to Settle False Billing Charges

Case: The feds claim that over an 11-year period the physician and his metropolitan Detroit area practice and lab sites violated the False Claims Act by billing Medicare, Medicaid and TRICARE for tests that were either not medically necessary or not performed at all, including Ankle Brachial Index and Toe Brachial Index (ABI/TBIs) tests. The ABI compares blood pressure in the ankle to blood pressure in the arm to evaluate blood flow; the TBI is an addition test to assess blood pressure readings at the toes. The investigators also found that the physician routinely ordered unnecessary Nuclear Stress Tests, a high-priced diagnostic procedure in which a small amount of radioactive tracer is injected into a vein to enable a special camera to produce images evaluating blood flow to the heart.

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Significance: The cardiologist was also one of the eight physicians involved in the alleged Beaumont Health system kickbacks scheme which was settled for $84.5 million in 2018. So, it's not surprising that as part of the settlement, the cardiologist agreed to enter into a 3-year Integrity Agreement. Both cases began as whistleblower lawsuits.

Simply Ordering Tests Doesn't Make Departing Physician Liable for Failure to Diagnose and Treat

Case: A Wisconsin inmate sued the prison's medical staff for failing to diagnose and treat his hepatitis C infection. Among the defendants was the physician who ordered the lab tests revealing the extremely high level of liver enzymes in the inmate's blood. So, the fact that the physician didn't tell the inmate that he had hepatitis C and get him some treatment was negligence, the lawsuit alleged. But the physician had a legitimate explanation for not following up: He had left the prison and taken another job by the time the test results came back. While not satisfying the inmate, the physician's explanation satisfied the Wisconsin federal court which tossed the claim against him without a trial.

Significance: As the court explained, the mere fact that the physician ordered tests ordered tests isn't enough to prove that he disregarded the inmate's serious medical needs or acted negligently. The silver lining for the inmate was that dismissal of the case against the ordering physician didn't get the treating physician who subsequently took over the case off the hook [*Jackson v. Lorenz*, 2021 U.S. Dist. LEXIS 36289, 2021 WL 765022].

EHR Technology Vendor Settles Kickback Charges for $18.25 Million

Case: Athenahealth Inc., a Massachusetts-based EHR software vendor has agreed to fork over $18.25 million to settle charges of paying kickbacks to generate sales. The DOJ complaint cites three marketing programs that allegedly crossed the line:

- A "Concierge Events" program offering customers and prospects free tickets and trips to high-profile sporting events like the Kentucky Derby;
- A "Lead Generation" program paying existing customers $3,000 for each new client they signed up regardless of how much time and effort they spent in the effort; and
- Deals paying competing EHR vendors who were closing shop fees and other remuneration for converting their clients into Athenahealth Inc. clients based on the value and volume of converted practices.

Significance: Even though Athenahealth Inc. is an EHR vendor rather than a lab, the marketing arrangements involved in the case raise kickbacks red flags regardless of the types of providers involved. Accordingly, be sure that the marketing efforts of your own lab don't involve any of these problematic activities.

Kickbacks: The HDL Saga Continues with $114 Million Verdict against Lab's CEO and Marketing Principles

Health Diagnostics Laboratory, Inc. (HDL) has been gone for years but prosecution efforts targeting the massive kickback scandal it authored lives on. Naturally, the initial wave of actions targeted the lab and its partner in crime, Singulex. But as soon as those cases wound up, attention shifted to others involved in the scheme, including BlueWave Healthcare Consultants (BlueWave), HDL and Singulex's marketing firm, and then to the downstream physicians to whom the labs directed their kickbacks. But now HDL itself is back in the spotlight, not the lab but the individual principles who were in charge when the scam unfolded. The most recent enforcement event of note occurred on Feb. 22, 2021, when the U.S. Court of Appeals for the Fourth Circuit upheld a massive $114.1 million jury verdict against a former blood lab chief executive officer and two sales consultants in a whistleblower case. Here's what happened and what it portends.

The HDL Scandal

The U.S. Anti-Kickback Statute (AKS) makes it illegal to offer, pay, solicit or receive remuneration to induce referrals of lab tests or other items or services covered by federally funded programs. The point of the AKS, and its physician referral cousin the Stark Law, is to ensure that physicians make medical treatment decisions based on the best interests of the patient without being influenced by bribes and improper financial incentives.

The HDL/Singulex scandal has become the poster child of kickoff abuse, at least within the labs sector. For sheer dollars involved, it's the biggest AKS prosecution ever undertaken against a lab. Some have even described it as the mother of all clinical lab frauds. For those of you unfamiliar with it, the case began as a qui tam lawsuit accusing HDL, Singulex and one other lab (the now defunct Berkeley Heart Lab) of conspiring with BlueWave to generate blood testing referrals, including medically unnecessary large multi-assay panels, by paying physicians sham specimen processing and handling fees of between $10 to $17 per referral and routinely waiving copayments and deductibles. Then, by billing Medicare, Medicaid and TRICARE for tests provided under the arrangement, the labs also violated the False Claims Act (FCA).

In April 2015, HDL paid $47 million to settle the charges against it; Singulex settled for $1.5 million. Both labs also entered into corporate integrity agreements with the government. The settlement forced HDL into Chapter 11 bankruptcy, but the embattled lab giant's legal woes continued. In addition to its creditors, HDL was sued by Cigna for $84 million in damages the private payer allegedly suffered as a result of the scheme. Adding insult to injury, BlueWave also sued its former partner for millions in unpaid consulting fees.

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The $114.1 Million Verdict against the HDL Principles

But the federal HDL crackdown was just heating up. The 2015 settlement covered just the labs themselves. And it is U.S. Justice Department policy (known as the Yates Memo after the author who codified it) to target corporate principles and hold them personally accountable for an organization's wrongdoing. In this case, the principles were HDL's former CEO and a pair of individuals involved in marketing HDL and Singulex tests. Unlike the labs they led, the individual defendants decided to fight it out in court.

It turned out to be an unwise decision. In May 2018, after a two-week trial, a South Carolina U.S. District Court jury found the three defendants liable for AKS and FCA violations. In May 2018, the U.S. obtained a judgment against three individuals for paying kickbacks for lab referrals and making claims for medically unnecessary tests. The dimensions of the scheme were staggering. Consider these numbers:

- **35,074:** The number of false claims by HDL the defendants were responsible for submitting to Medicare and TRICARE;
- **$16,601,591:** The total value of those claims;
- **3,813:** The number of false claims by Singulex the two marketing defendants were responsible for submitting to Medicare and TRICARE; and
- **$467,953:** The value of those claims.

Having established liability, the court then had to decide on a damage award. As the FCA allows, the court trebled the damage amounts, offset settlement payments received from HDL and Singulex for the same claims, and awarded $63.8 million in penalties requested by the U.S. Total judgment amount: $114,148,661.86.

The Appeal

The defendants cried foul, claiming that the government didn't prove that they "knowingly and willfully" violated the AKS. All we did was pay salespeople commissions, they insisted. But on Feb. 22, the U.S. Court of Appeals for the Fourth Circuit rejected the appeal and upheld the verdict—all $114.1 million of it.

So, now the defendants face the task of coming up with the money. Making their situation even more precarious is that their liability is "joint and several." In other words, the government can collect some, all or any amount of the judgment from any one or combination of the defendants. That basically means they can go after whoever has the deepest pockets.

Takeaway

The HDL case is still not over. There are still other principles to prosecute. In addition, in the past couple of years, the DOJ has collected over $1 million in settlements from physicians who allegedly accepted the bogus specimen collection fees and other kickbacks from HDL and Singulex.

Brief Your CEO: New OCR Data Shed Light on the Costs of Privacy Noncompliance

Getting lab officers to shell out money for compliance initiatives may be trickier when the penalties you're trying to head off are for privacy violations. After all, HIPAA penalties tend to be fairly modest compared to those handed out for *False Claims Act* (FCA), kickbacks and other health care fraud laws. But that shouldn't dissuade you, even though HIPAA enforcement is much less of a government cash cow than FCA and kickback enforcement, it remains an ongoing challenge. And when labs and other providers do get busted, it takes a lot of money out of their pockets and into the hands of the federal government.

Making the Business Case for HIPAA Compliance

As a lab compliance officer, you face the challenge of making this case to your CEO and/or CFO. Unfortunately, tracking the economics of HIPAA enforcement is relatively tricky because the government doesn't publish data on HIPAA recovery amounts the way it does with the FCA. However, new data from the HHS Office of Civil Rights (OCR) has recently emerged that offers some rare insight into the dollars and cents of HIPAA enforcement over the past two decades. Here are some of the key figures, which encompass April 2003, when HIPAA first began being enforced, through 2020, that you want to run past your lab officers:

- **$129,722,482:** Total amount of civil penalties and settlements collected by OCR for HIPAA infractions;
- **$26 Million:** Highest one-year total collected in past five years (2018);
- **$12 Million:** Lowest one-year total collected in past five years (2019);
- **$16 Million:** The highest ever settlement for a HIPAA violation, paid by Anthem in 2018 for a massive 2015 data breach affecting 79 million people;
- **250,367:** Total number of HIPAA complaints received by OCR;
- **3,992:** Number of HIPAA complaints that remain open (2 percent of total complaints filed); and
- **$129,722,482:** Total amount of civil penalties and settlements collected by OCR for HIPAA infractions.

Top 5 HIPAA Complaints

The OCR report also lists the top 5 most frequent reasons that people file HIPAA complaints:

1. Impermissible use or disclosure of an individual's protected health information (PHI);
2. Lack of adequate safeguards for PHI;

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3. Lack of patient access to their PHI;
4. Lack of proper administrative safeguards for electronic PHI; and
5. Use or disclosure of more than the necessary amount or type of PHI.

Takeaway

From a lab compliance officer's perspective, perhaps the most meaningful number listed in the OCR report is 69, which is the percentage of HIPAA complaints that have resulted in a corrective action being taken against a provider. In other words, nearly 7 in 10 HIPAA complaints result in a fine and/or imposition of a corrective action. That's a factoid you might want to cite to your lab officers the next time you encounter resistance to HIPAA compliance initiatives.

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furnish the documentation needed to show that the services are medically necessary.

The nature of medical necessity disputes has changed since the early years of Medicare because clinical labs must now submit a diagnosis code on Medicare payment claims, and ordering physicians must provide labs diagnosis or other medical information required for the

lab to receive payment. In addition, national coverage determinations (NCDs) and local coverage determinations (LCDs) from Medicare administrative contractors (MACs) can sometimes help labs determine, in advance, whether Medicare will consider a test to be medically necessary. Here's a broad look at the various medical necessity rules, the practical problems they create and some potential ways to resolve them.

Medicare Medical Necessity Requirements

The fundamental rule is that Medicare covers only tests that are "reasonable and necessary" to diagnose or treat an illness or injury. A test can be found not "reasonable and necessary" for many reasons, including because:

- It's not medically necessary given the patient's diagnosis or condition;
- It's not safe and effective;
- It's experimental or investigational;
- It wasn't "ordered" in accordance with Medicare rules, i.e., where the ordering physician wasn't the "treating" physician, or didn't use the test results to diagnose or treat the patient's specific medical problem.

In many cases, when the lab receives the requisition and before it performs

the test, the only information it has about the test is the information listed in the completed test requisition. However, this information doesn't provide anything potentially indicating that the ordered test isn't reasonable and necessary. In fact, based on the diagnosis information that the physician provides, it may appear that the ordered test does meet the medical necessity requirements listed in an NCD or LCD. However, it may turn out that the ordering physician's medical records do not support coverage of the test. Maybe the test "order" wasn't reflected in the patient's medical record; maybe the medical record entry wasn't properly authenticated; or perhaps the content of the medical record didn't support the diagnosis code included on the requisition.

In addition, more than one MAC has found medical records inadequate when they didn't explain the reason that certain tests were ordered, i.e., provide a "nexus" between the patient's signs and symptoms and the tests that were ordered. Result: The lab may only learn of the reasonable and necessary problem(s) later during a subsequent post-payment audit.

Medicare Financial Protection Provisions

The other key law shaping medical necessity is the parts of the Medicare statute (Section 42 1395pp(a)) that limit liability for services furnished by a provider that are determined not to be reasonable and necessary. The Rule: Medicare will pay the provider for these services, as long as neither the individual for whom the services were furnished nor the provider knew, or could reasonably have been expected to know, that Medicare wouldn't reimburse the services.

The Medicare statute also says that overpayments shouldn't be recovered from a provider if it was "without fault," i.e., exercised reasonable care in billing and accepting Medicare payment (42 U.S.C. § 1395gg(b)), as long as the provider has made full disclosure of all material facts and, based on the information available to the provider, it had a reasonable basis for assuming that the payment that it received was correct. MACs and other Medicare auditing organizations are specifically required to make a limitation of liability and "without fault" determination when a claim is denied because an item or service isn't reasonable and necessary.

How the Rules Play Out in Real Life

Based on these limitations of liability and "without fault" rules, labs seem to have a strong case for not being required to forego payment or repay amounts previously received for services that were determined not to be reasonable and necessary when the only basis for denying the claims was the content of the physician's medical records. In fact, such arguments were apparently accepted on a frequent basis during Medicare's earlier years. Unfortunately, they don't work nearly as well nowadays. There seems to be at least three reasons for that:

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First, in several cases, there may have been significant question whether the provider furnishing the services was independent of the ordering physician, such that it actually had no reason to believe that the services ordered by the physician weren't medically necessary.

Second, the Medicare Appeals Council and courts reviewing its decisions have permitted the statutory obligation of the entity seeking Medicare payments to provide documentation supporting its claims to trump any argument based on the supplier's lack of knowledge of the reasons for which the test was ordered, how the results were used, or its lack of access to related medical record documentation.

Third, even though regulations require only that the lab maintain documentation received from the ordering physician and documentation demonstrating that its Medicare claim accurately reflected that information, a lab's failure to provide additional documentation supporting medical necessity has resulted in denial of claims for payment (See, for example, *Meridian Laboratory Corp. v. AdvanceMed Corp.* (PSC), Departmental Appeals Board, Decision of Medicare Appeals Council, 2011 WL 6960470].

CMS Understands the Lab's Problem

In one recent decision involving tests furnished by an independent diagnostic testing facility (IDTF), the council stated that the "entity submitting the claim for its services will not receive Medicare coverage ... unless the services are documented as reasonable, necessary, and otherwise in compliance with Medicare requirements." The council recognized that "providers of laboratory ... services are dependent upon the ordering physicians to provide part of the documentation required to obtain Medicare coverage for their services."

However, it went on to hold that the IDTF was financially responsible for the services that it furnished when it was couldn't provide documentation to support their medical necessity. According to the council, "Medicare's documentation requirements are not intended to make ... laboratories ... the reviewers of the medical necessity, but rather require those entities, if they are going to bill Medicare, to support their claim for payment with documentation showing that the service is a service covered by Medicare" [*Virtual Imaging Services v. First Coast Service Options, Departmental Appeals Board Decision of Medicare Appeals Council*, M-14-1254].

In addition, findings that a provider knew or had reason to know that a claim would be denied have been supported by only the thinnest of reeds. In an appellate decision frequently cited by HHS, the court relied on regulations stating that a provider is deemed to know the content of manual issuances, bulletins, and other written guidelines provided by CMS or the MAC. According to the court, since these guidelines indicated

that the supplier was responsible for supporting medical necessity with documents that were generally in the possession of the ordering physician, it had sufficient notice that Medicare might require such documentation and would deny the claim if it wasn't provided. So, although it didn't explicitly say that the provider knew or could have been expected to know "that payment would not be made," the court upheld the council's decision not to afford the supplier protection under the statute's limitation of liability provisions [*Maximum Comfort, Inc. v. Secretary*, 512 F. 3d 1081, 1088-89 (9th Cir. 2007)].

4 Ways to Protect Your Lab from Medical Necessity Claims Denials

While the medical necessity issue may look like a "blame the victim" situations, there are at least four actions you can take to protect your lab against denials of Medicare claims based solely on the content of the physician's medical record or the lab's lack of access to those records.

1. Educate Physicians

First, the lab can educate physicians about its need for a copy of the physician's medical records to support the medical necessity of clinical lab tests that the physician orders.

2. Impose Contractual Obligations

If there's a contractual relationship, the lab should consider including a provision requiring the physician or medical group to provide medical record documentation upon the lab's request. In fact, Medicare regulations permit the lab to request such documents from the physician (42 C.F.R. § 410.32(d)(2), (3)). At least one MAC has indicated that a physician's failure to cooperate with a supplier violates a legal requirement. The regulations also provide for CMS to request such documents from the ordering physician and deny the claim if it doesn't receive them.

3. Ask Physicians to Personally Sign Requisitions

Labs should also encourage referring physicians to personally sign test requisitions. Although CMS has stated that this isn't required by Medicare regulations, getting a signed requisition can eliminate risk of assertions that:

- The test wasn't "ordered";
- The lab didn't provide documentation of the test order; and/or
- The order wasn't authenticated as required by Medicare regulations.

4. Secure ABNs

A lab should also confirm that it's obtaining Advance Beneficiary Notices of Noncoverage (ABNs) whenever appropriate and that it's encouraging physicians to do so on its behalf when the individual for whom testing is to be performed doesn't personally present at a lab patient service center.

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Takeaway

Medicare medical necessity requirements will continue to raise troublesome issues for labs. However, there are things labs can and should do to limit their financial exposure. They can also continue to make the case for protection from liability for services later found not be reasonable and necessary under the limitation of liability provisions of the Medicare statute.

Sidebar: The Proposed Official Medicare Coverage Definition of "Reasonable and Necessary"

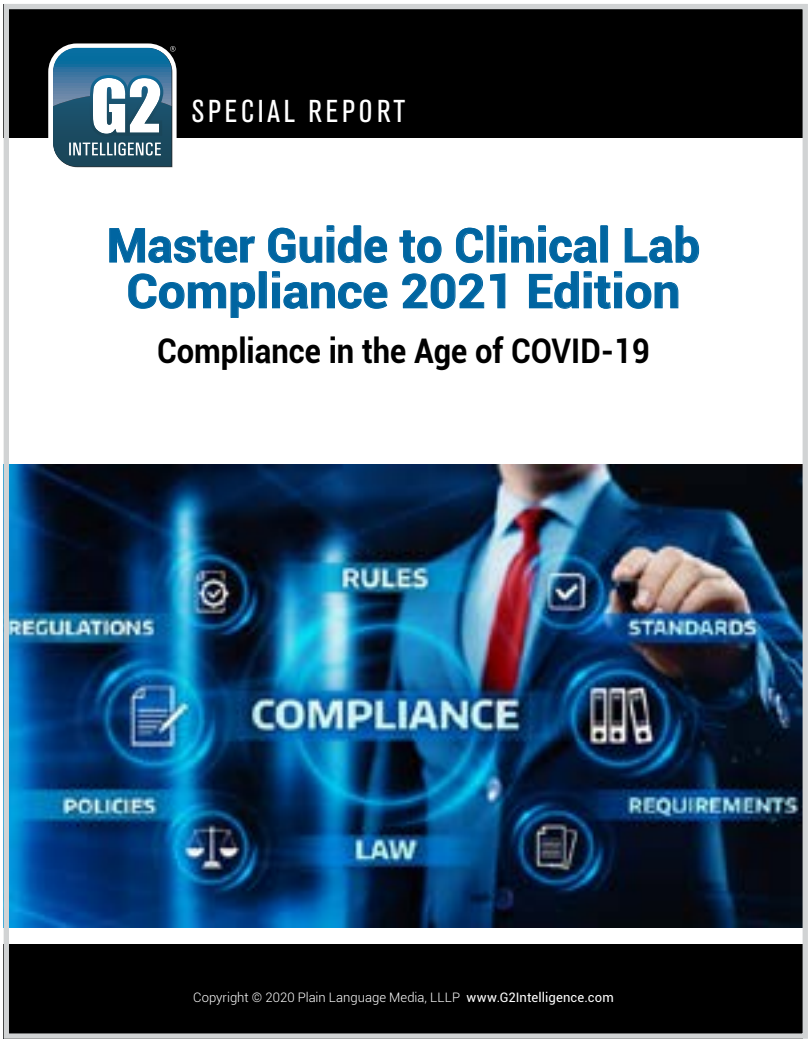
CMS is currently reviewing several regulatory changes that the Trump administration initiated in its final days. Among these "midnight regulations" is the Jan. 14 final rule establishing a definition for CMS to use to determine whether a service or item is "reasonable and necessary" for purposes of Medicare coverage. Under the final rule, a service or item would be deemed reasonable and necessary if it's considered:

- Safe and effective;
- Not experimental and investigational;
- Appropriate for Medicare patients to the extent it's: A. Furnished in accordance with accepted medical standards for diagnosis and treatment; B. Furnished in an appropriate setting; C. Ordered and provided by qualified personnel; D. Meets, but doesn't exceed, the patient's medical need; E. Is at least as beneficial as an existing and available medically appropriate alternative; or. F. Meets criteria to be created by CMS later measuring utilization and coverage of the service or item by commercial insurers.

The new rule was supposed to take effect on March 15.

Master Guide to Clinical Lab Compliance 2021

Compliance in the Age of COVID-19



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