

Weekly News and Compliance Strategies on Federal Regulations,  
Enforcement Actions and Audits

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## CMS OKs Provider-Based Billing for Telehealth Without Facility Fees After PHE Ends

In a breakthrough for hospitals, CMS says their provider-based departments will be able to bill Medicare for professional services delivered by telehealth to patients at home after the public health emergency (PHE) ends May 11 without corresponding facility fees. In other words, provider-based departments won't jeopardize their status if they bill only professional fees.

A CMS spokesperson told RMC that "after the end of the COVID-19 PHE, when a practitioner located in a hospital-based clinic furnishes a Medicare telehealth service, the hospital will no longer be able to bill for either the hospital clinic visit (HCPCS code G0463) or the originating site facility fee (HCPCS code Q3014). However, the practitioner may bill separately for their professional services provided all other Medicare telehealth requirements are met."

This is welcome news for hospitals, said attorney Andrew Ruskin, with K&L Gates in Washington, D.C. It wasn't clear things would turn out that way. He said Medicare regulations at 42 C.F.R. § 413.65(g)(5) require all Medicare patients treated in hospital outpatient departments to be billed as hospital outpatients, which CMS has sometimes interpreted historically as requiring all bills to have a hospital outpatient place of service. Claims for telehealth services delivered by a treating clinician sitting in provider-based space after the PHE expires won't have one of those place-of-service codes. That raised the question of whether provider-based departments could bill

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## RACs Eye Cardiac, Pulmonary Rehab; Treatment Plans Are Vulnerable, COVID-19 Is Included

Treatment plans that are cookie cutter, unsigned and otherwise noncompliant put claims for cardiac rehabilitation and pulmonary rehabilitation at risk of denial, experts say. With cardiac and pulmonary rehab on the recovery audit contractor (RAC) hit list and CMS adding COVID-19 as another covered diagnosis for pulmonary rehab, they might be ripe for an internal review. But improving compliance may be complicated by the fact that Medicare requirements aren't always detailed enough, according to the HHS Office of Inspector General (OIG).<sup>1</sup>

On the one hand, the 2021 audit of 100 claims for cardiac and pulmonary rehab submitted by one provider found errors on all of them. On the other hand, OIG "was pointing the finger at CMS for these errors, saying it has not been clear enough about some of the regulations and guidance," said Georgia Rackley, a senior clinical specialist at SunStone Consulting.

Some Medicare requirements for cardiac and pulmonary rehab, however, are black and white, such as physicians signing individualized treatment plans every 30 days (see checklists, pages 3 and 4). Wanda Cidor, a manager in the Deloitte & Touche advisory practice, said physicians failing to review and sign them timely is one of the top mistakes in this area. That's presumably something RACs look at in their reviews, which focus

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on whether cardiac and pulmonary rehab is medically necessary and meets Medicare coverage criteria.<sup>2</sup>

Cardiac rehab, intensive cardiac rehab and pulmonary rehab are outpatient physician-supervised programs that include exercise, education, counseling, behavioral intervention, psychosocial intervention and an outcomes assessment. Medicare covers cardiac rehab for patients who had an acute myocardial infarction within the preceding 12 months, coronary artery bypass surgery, have current stable angina pectoris, had heart valve repair or replacement, percutaneous transluminal coronary angioplasty, coronary stenting, a heart or heart-lung transplant, stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35% or less and New York Heart Association class II to IV symptoms despite being on optimal heart failure therapy for at least six weeks. Medicare covers pulmonary rehab for patients with moderate to very severe chronic obstructive pulmonary disease (defined as GOLD classification II, III and IV) when they're referred by the physician treating the chronic respiratory disease. CMS extended coverage for patients "who have had confirmed or suspected COVID-19 and experience persistent symptoms that include respiratory dysfunction for at least four weeks (effective January 1, 2022)," according to Medicare Transmittal 11,426.<sup>3</sup>

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Hospitals must meet certain requirements to qualify for payment. They include individualized treatment plans that are "established, reviewed and signed every 30 days by a physician involved in the beneficiary's care," according to OIG's report. The treatment plans are required to describe "(1) the beneficiary's diagnosis; (2) the type, amount, frequency, and duration of the items and services under the plan; and (3) the goals set for the individual under the plan." Physicians also must provide direct supervision of cardiac and pulmonary rehab.

### 'They Can't Be One-Size-Fits-All'

Hospitals with cardiac and pulmonary rehab programs may find their claims denied because treatment plans are not individualized, Cidor said. "They can't be one-size-fits-all," she noted. Treatment plans that use the same language for all patients or that come in checkbox format may not satisfy Medicare requirements, she said. "If I read five treatment plans, they could all be the same." It's not individualized or detailed enough if it just says the patient had a stent implanted and is able to complete cardiac rehab. Treatment plans should specify, for example, that the patient will exercise three times a week for 20 minutes on an exercise bike, Cidor said.

She has found, however, that "the biggest risk" is not completing treatment plans on time. Unless a treatment plan is written and signed by the physician before treatment begins, the hospital can't bill Medicare for the rehab, Cidor explained. "What we have seen is cardiac rehab staff develops the treatment plan, but the physician has to review it and agree to it before the patient can participate," she said. If treatment starts before that happens—for example, the physician signs on day three of rehab—the hospital isn't permitted to bill Medicare for the first three days. And the process must be repeated every 30 days.

Another kind of timing is also a big risk, Rackley said. She has seen providers bill for cardiac and pulmonary rehab sessions without crossing the threshold required by Medicare. "The rules are very clear you can't bill professionally for cardiac sessions unless they are 31 minutes long," she noted. Sessions that only last 28 minutes, for example, aren't long enough to bill for CPT code 93797 (physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ECG monitoring) or 93798 (same thing, only with continuous ECG monitoring).

But the OIG report found problems with Medicare's expectations. For example, the regulations on cardiac and pulmonary rehab don't "clearly explain what providers are required to document in an individualized treatment plan to ensure that a beneficiary's specific medical needs are adequately addressed."

## CMS Is Vague About Psychosocial Assessments

Providers also may drop the ball with their documentation of the psychosocial assessment, Cidor and Rackley said. "That's often not completed to the level of detail CMS is looking for," Cidor noted. As OIG explained in its report, "Cardiac and intensive cardiac rehabilitation programs must include an evaluation of a beneficiary's mental and emotional functioning as it relates to their rehabilitation, including an assessment of those aspects of a beneficiary's family and home situation that affects their rehabilitation treatment. These programs must also include a psychosocial evaluation of

the beneficiary's response to and rate of progress under the treatment plan (42 CFR § 410.49)." The same goes for pulmonary rehab psychosocial assessments.

But OIG said Medicare coverage requirements don't clearly explain how providers should document their evaluation of a patient's mental and emotional status and family and home situation. As a result, the provider that was the target of the audit "may not have clearly understood what documentation was required to support that an adequate psychosocial assessment was performed." For 75 days of the days sampled by OIG, the section of the treatment plan called "psychosocial intervention" had

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## Documentation Audit Tool for Cardiac Rehabilitation Program Requirements

This tool was developed by Georgia Rackley, a senior clinical specialist at SunStone Consulting (see story, p. 1). Cardiac and pulmonary rehab are on the approved list of audit targets of recovery audit contractors. Contact her at [georgiarackley@sunstoneconsulting.com](mailto:georgiarackley@sunstoneconsulting.com).

Requirement	Detail	Yes	No
Physician referral to admit to cardiac rehabilitation program			
<ul style="list-style-type: none"> <li>Acute myocardial infarction within the preceding 12 months</li> <li>Coronary artery bypass surgery</li> <li>Current stable angina pectoris</li> <li>Heart valve repair or replacement</li> <li>Percutaneous transluminal coronary angioplasty or coronary stenting</li> <li>Heart or heart-lung transplant</li> <li>Stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35% or less and New York Heart Association class II to IV symptoms despite being on optimal heart failure therapy for at least six weeks</li> </ul>	<ul style="list-style-type: none"> <li>Documentation that patient experienced one or more of these criteria.</li> </ul>		
Supervising physician is immediately available and accessible for medical consultations and emergencies at all times or direct supervision if office based	<ul style="list-style-type: none"> <li>Documentation to support physician availability (hospital based) or direct supervision (office based), e.g., physician daily log.</li> </ul>		
Individualized Treatment Plan	<ul style="list-style-type: none"> <li>Description of patient diagnosis.</li> <li>Physician signed prior to or on start date of treatment sessions; then physician reviewed and signed every 30 days.</li> <li>Must indicate the type, amount, frequency and duration of CR items and services.</li> <li>Must include patient specific goals for treatment.</li> </ul>		
Physician prescribed exercise program	<ul style="list-style-type: none"> <li>Validate for each day CR furnished, aerobic exercise combined with other types of exercise (such as strengthening and stretching) as determined to be appropriate for individual patients by the physician.</li> </ul>		
Cardiac risk factor modification, including education, counseling and behavioral intervention, tailored to the individual's needs	<ul style="list-style-type: none"> <li>Evidence of patient individualized education, counseling and behavior intervention that addresses cardiac risks.</li> </ul>		
Psychosocial assessment	<ul style="list-style-type: none"> <li>Written evaluation of patient's mental and emotional functioning relating to the patient's rehabilitation.</li> <li>Includes family and home situation that may affect the individual's rehabilitation treatment.</li> <li>Psychosocial evaluation of the individual's response to and rate of progress under the treatment plan.</li> </ul>		
Outcomes assessment of patient's progress	<ul style="list-style-type: none"> <li>Beginning and end evaluations based on patient centered outcomes conducted by the physician or staff at start and end of program.</li> <li>Should include objective clinical measures of exercise performance and self-reported measures of exertion and behavior.</li> </ul>		

little information about the patient's mental and emotional situation and progress in the program. OIG said 27 of them had only the comment "coping well."

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### Endnotes

1. Amy J. Frontz, *CMS Needs To Strengthen Regulatory Requirements For Medicare Part B Outpatient Cardiac And Pulmonary Rehabilitation Services To Ensure Providers Fully Meet Coverage Requirements*, A-02-18-01026, U.S. Department of Health & Human Services, Office of Inspector General, May 2021, <https://bit.ly/41sGS1m>.
2. Centers for Medicare & Medicaid Services, "0135-Cardiac Rehabilitation: Medical Necessity and Documentation Requirements," January 8, 2019, <https://go.cms.gov/3LdRmMa>.
3. An Omnibus CR Covering: (1) Removal of Two National Coverage Determination (NCDs), (2) Updates to the Medical

Nutrition Therapy (MNT) Policy, and (3) Updates to the Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR), and Intensive Cardiac Rehabilitation (ICR) Conditions of Coverage, Trans. 11,426, May 20, 2022, <https://go.cms.gov/3LeyP28>.

## FCA Settlement Alleges Billing for Services by Unsupervised Residents

Meharry Medical College in Nashville, Tennessee, has agreed to pay \$100,749 to settle false claims allegations that it billed Medicare for certain services provided by unsupervised, nonphysician residents, the U.S. Attorney's Office for the Middle District of Tennessee said April 17.<sup>1</sup> The settlement also requires Meharry to implement a policy on billing for residents and train faculty accordingly.

The government alleged that Meharry submitted false claims to Medicare Part B for physician services provided at

### Documentation Audit Tool for Pulmonary Rehabilitation Program Requirements

This tool was developed by Georgia Rackley, a senior clinical specialist at SunStone Consulting (see story, p. 1). Cardiac and pulmonary rehab are on the approved list of audit targets of recovery audit contractors. Contact her at [georgiarackley@sunstoneconsulting.com](mailto:georgiarackley@sunstoneconsulting.com).

Requirement	Detail	Yes	No
Physician referral to admit to pulmonary rehabilitation program			
Patient has moderate to very severe COPD; GOLD Classification II, III or IV; OR patient has confirmed or suspected COVID-19 and experience persistent symptoms that include respiratory dysfunction for at least four weeks	<ul style="list-style-type: none"> <li>• Physician documented validation of GOLD Classification; results of PFT should support this.</li> <li>• Physician validation of diagnosis and respiratory dysfunction for at least four weeks.</li> </ul>		
Supervising physician is immediately available and accessible for medical consultations and emergencies at all times or direct supervision if office based	<ul style="list-style-type: none"> <li>• Documentation to support physician availability (hospital based) or direct supervision (office based), e.g. physician daily log.</li> <li>• Direct supervision must be furnished by a doctor of medicine or osteopathy; non-physician practitioner cannot provide supervision.</li> </ul>		
Individualized treatment plan	<ul style="list-style-type: none"> <li>• Physician signed prior to or on start date of treatment sessions; then physician reviewed and signed every 30 days.</li> <li>• The plan must indicate the type, amount, frequency and duration of PR items and services.</li> <li>• Must include measurable and expected outcomes and estimated timetables to achieve these outcomes.</li> </ul>		
Physician prescribed exercise program	<ul style="list-style-type: none"> <li>• Aerobic exercise must be included in each PR session.</li> <li>• Target intensity (e.g., a specified percentage of the maximum predicted heart rate or number of METs).</li> <li>• Duration of each session (e.g., "20 minutes").</li> <li>• Frequency (number of sessions per week).</li> </ul>		
Patient education and training	<ul style="list-style-type: none"> <li>• Documentation of education and training that assists patient in achievement of individual goals toward independence in activities of daily living, adaptations to limitations and improved quality of life.</li> <li>• Must include information on respiratory problem management and, if appropriate, brief smoking cessation counseling.</li> </ul>		
Psychosocial assessment	<ul style="list-style-type: none"> <li>• Written evaluation of patient's mental and emotional functioning relating to the patient's rehabilitation or respiratory condition.</li> <li>• Includes family and home situation that may affect the individual's rehabilitation treatment.</li> <li>• Psychosocial evaluation of the individual's response to and rate of progress under the treatment plan.</li> </ul>		
Outcomes assessment of patient's progress	<ul style="list-style-type: none"> <li>• Beginning and ending evaluations based on patient-centered outcomes conducted by the physician or staff at start and end of program.</li> <li>• Should include objective clinical measures.</li> </ul>		



Nashville General Hospital when the services were actually performed by unsupervised nonphysician residents from Jan. 1, 2016, to March 15, 2020, according to the False Claims Act (FCA) settlement.<sup>2</sup> The services were provided in the internal medicine, OB/GYN and psychiatric outpatient clinics and in psychiatric consultations.

The dollar amount of the settlement was “modest” because most of the patients treated by the unsupervised residents were prisoners of the county and only some of the patients were covered by Medicare, said Gary Blackburn, the attorney for the whistleblower, Rachel Thomas, M.D., who set the case in motion. Nashville General Hospital is city owned and the city charter requires it to provide health care to indigent people, including prisoners, said Blackburn, with The Blackburn Firm PLLC.

The allegation of “county prisoners going to a [public] hospital getting unsupervised treatment by residents isn’t a great look,” said attorney David Vernon, with Hooper, Lundy & Bookman in Washington, D.C.

Meharry is also required by the settlement to adopt integrity measures:

- ◆ “Meharry will implement a Medicare billing policy designed to insure compliance with Medicare billing requirements for professional services provided by residents; and
- ◆ “For three years, Meharry will provide annual training to its faculty members and incoming first-year residents concerning Medicare billing requirements for professional services provided by residents.”

### **Some PHE Allowances for Physical Presence**

Meharry denied the whistleblower’s and government’s allegations in the settlement. An attorney for Meharry said “we are not in a position to comment.”

Teaching physician billing is a long-time risk area and has been at the heart of numerous settlements in the 30-plus years since the HHS Office of Inspector General (OIG) launched its Physicians at Teaching Hospitals (better known as PATH) audits, Vernon said. For example, Children’s Hospital Los Angeles Medical Group agreed to pay \$373,715 in 2021 to settle allegations with the OIG that it billed for radiology services performed by residents without “appropriate” supervision.<sup>3</sup>

Although Medicare pays graduate medical education (GME) payments for training residents, CMS also allows teaching physicians to bill separately under the Medicare Physician Fee Schedule when they directly perform services or when the resident performs services if the teaching physicians are physically present for the critical or key part of the service under 42 C.F.R. § 415.172, according to a May 2022 Medicare Learning Network (MLN) Booklet.<sup>4</sup>

The physical presence requirement has been relaxed during the COVID-19 public health emergency (PHE).

CMS appreciated the need for some flexibility, but it’s coming to an end May 11, and “we have to be careful and smart” when the usual requirements around physical presence are back in effect, Vernon said.

For example, during the PHE, teaching physicians are permitted to use audio/video real-time communications technology for interacting with the resident and complying with the physical presence requirement, according to CMS’s COVID-19 flexibilities fact sheet for teaching hospitals.<sup>5</sup>

CMS also made allowances during the PHE for certain primary care centers. Teaching physicians “can provide the necessary direction, management, and review for services furnished by up to four residents at a time using audio/video real-time communications technology,” the fact sheet states. “After the PHE, teaching physicians only in residency training sites located outside of a metropolitan statistical area may direct, manage, and review care furnished by residents through audio/video real-time communications technology.”

In the past couple of years, CMS has relaxed documentation requirements for physical presence. Teaching physicians are now free to let residents and nurses document most of their E/M services, as long as their physical presence is noted in the medical records, and physicians, physician assistants and advanced practice registered nurses who perform and bill for their professional services only have to verify, rather than redocument, information in the chart from the members of the medical team, including residents and nurses.

### **Relator Alleged Attendings Never Saw Patients**

Thomas, the whistleblower who filed the FCA lawsuit against Meharry, is a hospitalist who was hired in April 2019 by TeamHealth, which had a contract to staff the emergency room at Nashville General Hospital. According to her complaint, Medicare funds Meharry’s GME residency program and Nashville General Hospital participates in Meharry’s GME residency program.<sup>6</sup> The residents don’t have billing privileges and aren’t licensed to practice medicine. TeamHealth allegedly participates in Meharry’s GME residency program. TeamHealth and Nashville Community Hospital were named in the complaint but are not parties to the settlement.

“Relator discovered that the attending physicians never see the patients,” the complaint alleged.

For example, in June 2020, Thomas took on a psychiatric case at Meharry, which she said doesn’t have a telemedicine program in the hospital. “Although Medicare and the Accreditation Council for Graduate Medical Education (‘ACGME’) accreditation board require psychiatric patients to have an in-person evaluation by the attending physician, the attending physicians at Meharry fail to do so,” the complaint alleged. “Attending physicians

are solely responsible for signing the patients' charts, but they never see the psychiatric patients. Because they can sign the patient's chart electronically, they never have to go into the hospital to perform their rounds."

Blackburn, the attorney for Thomas, said there won't be any additional settlements in the case. "I don't think it's going to be useful for Dr. Thomas to pursue anything else," he said. "What she mainly wanted was to stop this" from happening and have "better care." Thomas is practicing elsewhere now in Tennessee.

Contact Vernon at [dvernon@hooperlundy.com](mailto:dvernon@hooperlundy.com) and Blackburn at [gblackburn@wgaryblackburn.com](mailto:gblackburn@wgaryblackburn.com). ✦

## Endnotes

1. U.S. Department of Justice, U.S. Attorney's Office for the Middle District of Tennessee, "Meharry Medical College Agrees To Settle False Claims Act Allegations," news release, April 17, 2023, <https://bit.ly/3mHgWjn>.
2. Settlement agreement, United States ex rel. Thomas v. Meharry Medical College, Case No. 3:20-cv-00658 (M.D. Tenn.), <https://bit.ly/43PdELL>.
3. Nina Youngstrom, "Medical Group Pays \$373,715 to Settle CMP Case on Supervision," *Report on Medicare Compliance* 30, no. 9 (March 8, 2021), <https://bit.ly/3MXunWP>.
4. MLN Booklet, *Teaching Physicians, Interns, & Residents Guidelines*, MLN006347, May 2022, <https://go.cms.gov/3LercsE>.
5. Centers for Medicare & Medicaid Services, "Teaching Hospitals, Teaching Physicians and Medical Residents: CMS Flexibilities to Fight COVID-19," March 31, 2023, <https://go.cms.gov/3oxwM0c>.
6. Complaint, United States ex rel. Thomas v. Meharry Medical College, Case No. 3:20-cv-00658 (M.D. Tenn.), <https://bit.ly/3N1cvdQ>.

## Consider Three-Step Process to Pivot to Post-PHE Loss of Stark Waivers

As an example of the way the Stark waivers in place during the COVID-19 public health emergency (PHE) have given hospitals a wide berth in their compensation relationships, they may have been able to pay hospitalists a higher hourly rate than they paid before the pandemic. But with the PHE ending May 11, hospitals may have to reduce hospitalist compensation, depending on the circumstances.

"If a portion is because of COVID, that has to be taken off the table," said attorney Bob Wade, with Nelson Mullins in Nashville, Tennessee. But if hospitals are able to justify continuing the above fair-market value compensation for other reasons, it may go back on the table even though it's no longer considered a COVID-19 differential, he said. Other reasons it could be justified include a demand for the specialty that exceeds supply "or ancillary issues impacting this physician," Wade said. This could be their experience, leadership and productivity.

That's the kind of analysis hospitals face with the PHE expiring and the waivers along with it. During the PHE, the analysis of Stark compliance focuses largely on whether an arrangement is fair market value and commercially reasonable—total cash compensation—"with an overlay of COVID-19," Wade said. "Now we have to take away the factor of the COVID impact on total cash compensation."

CMS announced blanket Stark waivers on March 30, 2020, to allow certain financial relationships and referrals that otherwise would invite sanctions, said Lyle Oelrich, a principal at PYA in Knoxville, Tennessee.<sup>1</sup> There are 18 waivers, half of which permitted compensation that was greater or less than fair market value, he said at a March 28 webinar sponsored by PYA. "They are also bidirectional," which means the waivers apply to compensation from an entity to a physician and vice versa. Other waivers allow arrangements that were not memorialized in writing.

Against this backdrop, there have been advances since March 2020 that affect financial relationships with physicians, Oelrich said. Hospitals and other health care organizations should keep these changes in mind as they move forward after the PHE ends.

For one thing, recent Medicare Physician Fee Schedule (MPFS) rules have significantly changed evaluation and management (E/M) work relative value units (work RVUs), which in some cases are used to calculate productivity compensation, Oelrich said. For example, the 2021 MPFS rule made big work RVU changes primarily on the outpatient side. At times, physicians on a work RVU compensation methodology may have been paid more than before the 2021 MPFS rule in the absence of mitigating factors, such as a change in their compensation conversion factor (i.e., compensation per work RVU), he said. Complicating matters was the fact that in many cases there was no reimbursement increase for hospitals. "We had one client with 500 physicians who was thinking about implementing the 2021 Medicare Physician Fee Schedule" for the purpose of paying physician compensation, Oelrich said. The loss would have exceeded \$35 million if the hospital had implemented the 2021 MPFS rule "without any mitigating efforts."

The work RVU changes in the 2023 MPFS rule primarily affect the inpatient side of the house. For example, Oelrich said he has seen estimates that hospitalists will experience a work RVU increase of 8% to 10%.

In another development, the Stark Law and Anti-Kickback Statute were revised in January 2021 and, among other things, the Stark regulation has a new definition of fair market value, a "codified definition" of commercial reasonableness and a volume or value of referrals standard. "Even if you were compliant prior to March 30, 2020, and

met the fair market value definition, you may not meet the new fair market value definition going forward as we reach the end of the PHE,” Oelrich said.

### Three-Step Process for Transition

To pivot to a world where there are no Stark waivers, hospitals and other organizations should consider a three-step process: identify, document and recalibrate, said Tynan Kugler, a principal at PYA in Atlanta. The reason for this process is to prepare for the scrutiny of arrangements that were entered into during the PHE.

For step one, organizations would determine whether they used any of the blanket waivers. Here are two examples from CMS’s waiver document:

- ◆ “A hospital pays physicians above their previously contracted rate for furnishing professional services for COVID-19 patients in particularly hazardous or challenging environments; and
- ◆ “To accommodate patient surge, a hospital rents office space or equipment from an independent physician practice at below fair market value or at no charge.”

The second step is to identify their documentation of arrangements that fell under the waiver’s criteria, Kugler said. She said organizations should identify the COVID-19 purpose of the waiver that they relied on and how the payment and compensation arrangement was established. “If people used these, there should be records you can go back to and say why you used the waivers and have documentation to back that up,” Kugler explained. This could be a checklist, memo to the file or other documentation that identifies the purposes, need and/or rationale specific to the arrangement.<sup>2</sup>

She cautions that the more time that passes, the harder it will be to find documentation to support the waivers. “With all the changes that occurred in staffing, you may not have the same staff you had at the start of the pandemic. It will be even more critical to identify who is maintaining this process and who will keep a history of records on a go-forward basis,” Kugler said.

Once organizations have identified the universe of arrangements under Stark waivers, she recommends stratifying them by their level of risk. The higher-risk arrangements should be reviewed first. For example, did the organization increase physician compensation and if so, why? What’s the documentation to support it and is the compensation bump still in effect and appropriate?

The third step is recalibration. “We anticipate a number of arrangements that relied on the waivers will need to be re-evaluated from a fair market value and commercial reasonableness perspective,” Kugler said. In terms of commercial reasonableness, your organization will have to decide whether there’s a legitimate business purpose for the deal when it’s not driven by the

pandemic. And with fair market value, “we’re talking about the amount of money exchanged between the two parties to the transaction,” Kugler explained.

If organizations determine they can’t meet a Stark exception without a waiver, among other regulatory requirements, “there is a decision that has to be made about terminating the arrangement.”

But can the compensation agreement be modified or terminated in the middle of it? The answer is yes, as long as the agreement has existed for one year, Wade said. “You can modify the services and amend the contract” as long as the compensation is fair market value and commercially reasonable.

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### Endnotes

1. Centers for Medicare & Medicaid Services, “Blanket Waivers of Section 1877(g) of the Social Security Act Due to Declaration of COVID-19 Outbreak in the United States as a National Emergency,” March 1, 2020, <https://go.cms.gov/2JuPI8a>.
2. PYA, “Stark Law Blanket Waiver Documentation Checklist,” March 30, 2020, <https://bit.ly/3mWtao7>.

## CMS Transmittals and Federal Register Regulations, April 14-April 20

### Transmittals

#### Pub. 100-04, Medicare Claims Processing

- Telehealth Code Reporting and Date Matching Edit for Home Health Claims, Trans. 11,964 (April 20, 2023)
- Religious Nonmedical Health Care Institution Provisions of the Consolidated Appropriations Act (CAA) of 2023, Trans. 11,963 (April 20, 2023)

#### Pub. 100-09, Medicare Contractor Beneficiary and Provider Communications

- Updates to Pub. 100-09, Chapter 6 Beneficiary and Provider Communications Manual, Chapter 6, Provider Customer Service Program, Trans. 11,956 (April 20, 2023)

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

- Addition of New Data Elements to the National Claims History (NCH) Claims Data Output, Trans. 11,971 (April 20, 2023)
- CMS Mammography Quality Standards Act (MQSA) File Reformatting, Trans. 11,985 (April 20, 2023)

#### Pub. 100-19, Demonstrations

- Update Existing Emails to Distribution List for CR 12791 - Implementation CR, Trans. 11,967 (April 20, 2023)

### Federal Register

#### Notice

- Medicaid Program; Final FY 2020, Final FY 2021, Preliminary FY 2022, and Preliminary FY 2023 Disproportionate Share Hospital Allotments, and Final FY 2020, Final FY 2021, Preliminary FY 2022, and Preliminary FY 2023 Institutions for Mental Diseases Disproportionate Share Hospital Limits, 88 Fed. Reg. 23,049 (April 14, 2023)



## CMS OKs New Angle for Provider-Based Billing

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just a professional fee for telehealth services delivered to patients at home. The answer now seems to be yes, Ruskin said. After all, a lot has changed since pre-COVID-19 days.

As the CMS spokesperson explained, during the PHE, Medicare patients have “broad access to telehealth services, including in their homes, without the geographic or location limits that usually apply” because of the COVID-19 waivers facilitated by the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, and the Coronavirus Aid, Relief, and Economic Security Act. Then the 2023 Consolidated Appropriations Act extended many telehealth flexibilities through the end of 2024. For example, “People with Medicare can access telehealth services in any geographic area in the United States, rather than only those in rural areas,” and “People with Medicare can stay in their homes for telehealth visits that

Medicare pays for rather than traveling to a health care facility.”

And now it looks like CMS is giving provider-based departments permission to bill Medicare for the professional fee without the facility fee when they deliver telehealth services to patients at home, Ruskin said.

“This is the asteroid no one knew was coming but nearly missed earth all the same. Hospitals would have been devastated if they first learned that CMS was enforcing its uniform billing rule only when their provider-based status was being terminated.”

Ruskin interprets CMS’s guidance as permitting providers to use telehealth place of service codes (02 and 10) without penalty even though they aren’t the hospital outpatient department place of service codes (19 and 22).

This development will be helpful to patients who have become accustomed to receiving care by telehealth and avoiding travel, especially if they’re vulnerable, he noted.

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## NEWS BRIEFS

◆ In an April 20 MLN Connects, CMS reminds providers they are required to respond timely to additional documentation requests.<sup>1</sup>

◆ The HHS Office of Inspector General (OIG) has updated its work plan and it includes an evaluation of “the use of remote patient monitoring services in Medicare,” which OIG said “has the potential to exponentially expand.”<sup>2</sup>

◆ Greater Boston Behavioral Health LLC has agreed to plead guilty to a misdemeanor charge of violating the Food, Drug and Cosmetic Act (FDCA), paying a criminal fine of \$657,678 and forfeiting \$1,929,464 in connection with the administration of a misbranded drug, the U.S. Attorney’s Office for the District of Massachusetts said April 20.<sup>3</sup> “According to the criminal information, Greater Boston Behavioral Health sought out sources from which it could purchase Botox® that was packaged and labeled only for sale in the United Kingdom and other foreign countries. The label of the foreign Botox purchased by Greater Boston Behavioral Health differed from the FDA-approved label for Botox and Botox Cosmetic and lacked the designation ‘Rx Only’ as required by the FDCA for prescription drugs,” the U.S. attorney’s office said. “The label also typically did not include the FDA-required ‘black-box warning’ concerning potential side-effects of Botox.”

◆ The U.S. Department of Justice (DOJ) said April 20 it has charged 18 people in nine federal districts with participating in schemes involving health care services that “exploited the COVID-19 pandemic.”<sup>4</sup> DOJ said it has seized \$16 million in connection with the enforcement action. In one of the major schemes cited, DOJ said it has charged multiple people with defrauding the Health Resources and Services Administration (HRSA) COVID-19 Uninsured Program. Also, CMS’s Center for Program Integrity separately announced that it has taken adverse administrative actions against 28 providers over the past year because of their “alleged involvement in COVID-19 schemes.”

◆ Two Miami, Florida, physicians were sentenced April 20 in connection with their convictions for Medicare fraud involving durable medical equipment (DME) that Medicare patients didn’t

want or need, DOJ said.<sup>5</sup> Dean Zusmer, a chiropractor, was sentenced to eight years and one month in prison and ordered to pay \$1.4 million in restitution while Lawrence Alexander, an orthopedic surgeon, was sentenced to two years and nine months in prison with restitution to be decided later. Zusmer owned one of four DME companies that charged Medicare over \$31 million for medically unnecessary DME, \$15 million of which was paid, DOJ said. Zusmer and his co-conspirators got hold of patient referrals and signed doctors’ orders by paying kickbacks to marketers who used overseas call centers to solicit patients and telemedicine companies to get prescriptions for unnecessary braces for the patients, DOJ said. Alexander owned one of the DME companies with a co-conspirator and hid his and the co-conspirator’s roles in the scam by putting the DME company in the name of a family member of Alexander’s. Zusmer was convicted at trial on multiple health fraud-related offenses and Alexander was convicted of one count of making a false statement relating to health care matters.

## Endnotes

1. Center for Medicare & Medicaid Services, “Medical Review & Compliance: Respond to Additional Documentation Requests,” MLN Connects, April 20, 2023, <https://bit.ly/3ovRzSa>.
2. U.S. Department of Health & Human Services, Office of Inspector General, “Use of Remote Patient Monitoring Services in Medicare,” revised April 2023, <https://bit.ly/3H01o0U>.
3. U.S. Department of Justice, U.S. Attorney’s Office for the District of Massachusetts, “Massachusetts Health Care Company Agrees to Plead Guilty and Pay More Than \$2.5 Million for Purchasing Botox That was Packaged and Labeled for Use Only in Foreign Countries,” news release, April 20, 2023, <https://bit.ly/3AgS5FY>.
4. U.S. Department of Justice, Office of Public Affairs, “Justice Department Announces Nationwide Coordinated Law Enforcement Action to Combat COVID-19 Health Care Fraud,” news release, April 20, 2023, <https://bit.ly/41tPy7y>.
5. U.S. Department of Justice, Office for Public Affairs, “Two Doctors Sentenced for Stealing \$31M From Medicare,” news release, April 20, 2023, <https://bit.ly/3MXy52W>.