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Medicare Reimbursement: The 6 Changes to the 2022 Physician Fee Schedule Most Likely to Affect Your Lab

CMS issued the final rule setting out the Medicare Part B Physician Fee Schedule (PFS) and Clinical Laboratory Fee Schedule (CLFS) for 2022. Here's a look at the six changes that are most likely to affect your lab's reimbursement in the coming year.

What's At Stake

Unlike most services provided in a physician's office for which Medicare pays at a single rate based on the full range of resources involved in furnishing the service, PFS rates paid to physicians ambulatory surgery centers (ASCs), hospital outpatient departments and other facility settings reflect only the portion of the resources typically incurred by the practitioner in furnishing the service.

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Compliance Perspectives: OIG Revises Self-Disclosure Protocol

On Nov. 8, the OIG did something it hadn't done since 2013: It revised the Provider Self-Disclosure Protocol. Here's a look at the six key changes to the protocol, which now has a new name, the Health Care Fraud Self-Disclosure Protocol (SDP)

What the SDP Does

First published in 1998, the SDP establishes a framework and process for labs and other providers to voluntarily disclose and resolve self-discovered overpayments, improper Anti-Kickback Statute (AKS) violations and other acts of potential fraud involving federal government health programs. According to the OIG, "self-disclosure gives persons the opportunity to avoid the costs and disruptions associated with

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Many of the diagnostic tests covered by the PFS are reimbursed in separate payments covering the services' professional and technical components. Typically, labs bill for the technical component and physicians bill for the professional component.

The 6 Key PFS Changes

The PFS rule runs over 1,000 pages but at the end of the day, these are the six items likely to make dollars-and-cents differences to most labs:

1. CLFS Phlebotomy Travel Allowances

Medicare pays a specimen collection fee when it's medically necessary for a clinical lab technician or other trained personnel (referred to collectively as "technicians") to draw a specimen for a test. If the technician travels to a nursing home or a homebound patient's residence for phlebotomy services (or to collect a specimen via catheterization), Medicare also pays a phlebotomy travel allowance covering transportation and personnel expenses. Labs are supposed to use one of two Healthcare Common Procedure Coding System (HCPCS) codes for phlebotomy travel allowances:

2022 Per Mile Travel Allowance (HCPCS P9603)

The per mile allowance is used when the average round trip to a patient's home or nursing home is farther than 20 miles, paid on a mileage per trip basis. The CLFS mileage rate for 2022 is $1.01 per mile, or higher if the Medicare Administrative Contractor (MAC) believes that local conditions warrant a higher rate.

2022 Flat Rate Travel Allowance (HCPCS P9604)

The flat rate per trip travel allowance is used when the average round trip is less than or equal to 20 miles. The 2022 flat rate will be $10.10 per trip.

Prorating Requirements

Under either code, when one trip is made for specimen draws or pickups from multiple patients (e.g., at a nursing home), the travel payment component is prorated based on the number of Medicare and non-Medicare patients on that trip. All draws and pickups are included in the proration, and the prorated phlebotomy travel allowance is billed on behalf of each Medicare patient.

CMS also clarified that it plans to make permanent the option for labs to maintain electronic logs of miles traveled for the purposes of covering the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a specimen sample.

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2. 9 % Cut in PFS Payment Rates

PFS payments are based on the relative resources typically used to furnish the service, expressed as relative value units (RVUs) covering the work, practice expense and malpractice expense. RVUs become payment rates via the application of a fixed-dollar conversion factor. CMS also makes geographic practice cost index adjustments to the total RVUs to account for variation in practice costs by geographic area. Payment rates are calculated to include an overall payment update specified by statute.

The bad news is that CMS is reducing Medicare payments to physicians by nearly Nine percent next year. This is based on the expiration of the temporary 3.75 percent increase physicians received in 2021 via the Consolidation Appropriations Act (CAA), and a PFS conversion factor of $33.59 (as opposed to the $34.89 conversion factor used in CY 2021).

3. Revisions to Billing Rules for Split (or Shared) E/M Visits

The 2022 PFS final rule revises CMS' longstanding policies for split (or shared) E/M visits to reflect the current medical practice, the evolving role of non-physician practitioners (NPPs) as members of the medical team, and to clarify conditions of payment that must be met to bill Medicare for these services. Specifically:

- A new definition of split (or shared) E/M visits as E/M visits provided in the facility setting by a physician and an NPP in the same group, with the visit billed by the physician or practitioner who provides the visit's substantive portion of the visit;
- For 2022, the substantive portion may include history, physical exam, medical decision-making, or more than half of the total time (except for critical care, which can only be more than half of the total time);
- By 2023, the substantive portion of the visit will be defined as more than half of the total time spent;
- Split (or shared) visits can be reported for new and established patients, as well as for initial and subsequent visits, and prolonged services;
- There must be a modifier on the claim to identify these services to inform policy and help ensure program integrity;
- Documentation in the medical record must identify the two individuals who performed the visit; and
- The individual providing the substantive portion must sign and date the medical record.

4. Changes to Billing & Payment of Critical Care Services

The final rule also makes a number of significant changes to billing and payment of critical care services. Effective Jan. 1, 2022:

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- The CPT Codebook listing of bundled services won't be separately payable;
- Medically necessary, critical care services can be furnished concurrently to the same patient on the same day by more than one practitioner representing more than one specialty, and as split (or shared) visits;
- Critical care services may be paid on the same day as other E/M visits by the same practitioner or another practitioner in the same group of the same specialty, if the practitioner documents that: i. the E/M visit was provided before the critical care service at a point when the patient didn't require critical care; ii. the visit was medically necessary, and; iii. the services are separate and distinct, with no duplicative elements from the critical care service provided later in the day (**Note:** Practitioners must report modifier -25 on the claim when reporting these critical care services);
- Critical care services may be paid separately in addition to a procedure with a global surgical period if the critical care is unrelated to the surgical procedure;
- Preoperative and/or postoperative critical care may be paid in addition to the procedure if: i. the patient is critically ill; ii. the patient requires the full attention of the physician; and iii. the critical care is above and beyond and unrelated to the specific anatomic injury or general surgical procedure performed (e.g., trauma, burn cases) (**Note:** CMS is creating a new modifier for such claims to identify that the critical care is unrelated to the procedure;
- If care is fully transferred from the surgeon to an intensivist (and the critical care is unrelated), the appropriate modifiers must also be reported to indicate the transfer of care; and
- Medical record documentation must support the above claims.

5. Changes to Physician Assistant (PA) Billing Rules

Starting Jan. 1, 2022, Medicare will make direct payments to PAs for professional services furnished under Part B. Previous rules required Medicare to make payment only to the employer or independent contractor of a PA. In addition to billing Medicare directly for their professional services, PAs can now reassign payment for their professional services and incorporate with other PAs and bill Medicare for PA services.

6. Changes to Telehealth Services Rules

Telehealth services that CMS temporarily added to the Medicare telehealth services list during the COVID-19 public health emergency will remain on the list through Dec. 31, 2023, giving the agency time to determine whether to add those services on a permanent basis.

In addition, CMS is eliminating geographic restrictions limiting patients' access to telehealth services for mental disorders and adding the home

of the beneficiary as a permissible originating site for telehealth services furnished for the purposes of diagnosis, evaluation, or treatment of a mental health disorder covered by Medicare. The physician or practitioner will still have to have visited the patient within six months before the initial telehealth service and then visit the patient after the telehealth session at a frequency to be determined by regulations.

Labs IN COURT

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

Florida Lab Owner Gets 82-Month Jail Sentence for Telemedicine Genetic Test Ripoff

Case: The Florida owner of multiple diagnostic labs will be spending 82 months in a federal prison after being convicted of generating kickbacks for genetic lab tests ordered via telehealth visits. The owner took advantage of temporary waivers put in place to ensure patients access to medical care during the public health emergency by paying off telehealth providers to order medically unnecessary cancer and cardiovascular genetic tests; in return, providers got access to personal information about the beneficiaries and the chance to bill for telehealth consultations, many of which never actually took place.

Significance: This case targeting the co-owners of Panda Conservation Group LLC is part of a larger COVID-19 health care fraud coordinated enforcement action spanning seven judicial districts against 14 defendants for allegedly exploiting the temporary regulatory waivers to generate illegal referral for genetic lab tests ordered via telehealth consultations. The DOJ has announced a series of such actions since the start of the pandemic.

Company Must Prove Bona Fide Employment Relationship AKS Safe Harbor at Trial

Case: According to the DOJ, physician-investors/employees of spinal implant distribution companies were paid a portion of company profits from sales of implant devices to Medicare patients. By then billing for spinal surgeries to implant the devices, the companies also submitted false claims. The companies insisted that its agreements with the physicians were perfectly legitimate under the Anti-Kickback Statute bona fide employment relationship safe harbor and asked the California federal court to dismiss the claims. The court refused.

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Significance: The safe harbor states that "any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered goods or services" doesn't constitute "illegal remuneration" under the AKS. The evidence showed that the investor-doctors did sign an employment agreement and keep timesheets. But that wasn't enough to justify dismissing the charge at this point. As a result, the case would have to go to trial where the companies would face the burden of proving they met all of the safe harbor requirements [*United States v. Reliance Med. Sys., LLC*, 2021 U.S. Dist. LEXIS 218111].

Texas MDs Pay $3.9 Million to Settle Claims of Falsely Billing Urine Drug Tests

Case: A pair of Texas physicians have agreed to pay $3.9 million to settle claims of billing Medicare, Medicaid and TRICARE for urine drug tests that they knew weren't medically necessary out of their now defunct in-house pain clinic lab. The former lab employee who brought the whistleblower claim that got this case started will receive a share of $618,000.

Significance: The feds claim that the physicians drafted the testing protocols that resulted in the performance of unnecessary tests knowing that the clinic needed the revenue from the tests to remain profitable. Even without whistleblower intervention, there's a pretty good chance that the excessive number of urine drug tests generated by the clinic would have been spotted by the enforcement establishment's radar [*United States ex rel. Nuessner, et al. v. Austin Pain Associates, LLC, et al.*, 5:16-CV-1125-FB (W.D. Tex.)].

Did Commission Agreement based on Lab Client Revenues Violate EKRA?

Case: When the new federal EKRA law extending kickback laws to private payors took effect in 2019, in-house counsel advised a urinalysis lab

that it had to restructure its current marketing employee arrangements basing commission payments on the percentage of tests generated by their clients. One of the affected employees was a client accounts manager caught up in a pre-existing dispute over alleged misappropriation of the lab's trade secrets, which prevented the sides from reaching agreement on a restructured compensation agreement. And since the current agreement didn't comply with EKRA, the lab decided to withhold his entire compensation and pay him the money retroactively if and when he signed a new deal. The sides ended up in litigation with the Hawaii federal court ruling in the employee's favor on the EKRA issue.

Significance: In a bit of a head scratcher, the court ruled that the employee's compensation arrangement didn't violate EKRA. True, basing commissions on test revenues generated by clients constituted remuneration under the law. However, the court continued, it didn't "induce a referral of an individual to" the lab. The employee's clients were the ordering physicians rather than the individuals tested. And the lab wasn't paid by these clients but by the test subject's payor. And because the compensation arrangement didn't violate EKRA, the lab's decision not to pay him violated both the contract and state labor standards law.

Enforcement News: OCR Continues HIPAA Right of Access Crackdown, but at a Much Slower Pace

Twenty different providers have been hit with fines since the Department of Health and Human Services' Office for Civil Rights (OCR) launched its HIPAA Right of Access Initiative in April 2019. However, the size of the fines has been relatively small, with only three reaching six figures. Perhaps more significantly, the pace of reported Access Initiatives has slowed noticeably since the new Biden administration.

Implication: Either the OCR isn't reporting settlements, or the new regime is less interested than its predecessor in pressing forward on access enforcement actions. Here's a summary of all of the reported settlements so far, including the most recent $80,000 action against a children's hospital in Nebraska.

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OCR Right of Access Initiative Settlements Scorecard (as of Sept. 27, 2021)

Provider	Settlement Amount*	Allegations
Banner Health ACE	$200,000	OCR cites two occasions in which Phoenix-based not-for-profit health system took about 6 months to provide patients their requested PHI
St. Joseph's Hospital and Medical Center	$160,000	Phoenix hospital refused to provide PHI to patient's mother even though she was his legal representative
NY Spine Medicine	$100,000	Neurology practice refuses patient's multiple requests for copies of specific diagnostic films
Bayfront Hospital	$85,000	Florida hospital didn't provide expectant mother timely access to the PHI of her unborn child
Korunda Medical	$85,000	After first refusing to provide it at all, Florida primary care and interventional pain management services provider sent patient's PHI to third party in the wrong format and charged him excessive fees
Children's Hospital & Medical Center	$80,000	Nebraska hospital denied mother of minor patient timely access to her daughter's medical records, despite repeated requests
Renown Health, P.C.	$75,000	Nevada private, not-for-profit health system didn't honor patient's request to transfer her EHR and billing records to a third party in a timely manner
Sharp Rees-Stealy Medical Centers	$70,000	California hospital and healthcare network didn't honor request to transfer patient's EHR to a third party in a timely manner
Beth Israel Lahey Health Behavioral Services	$70,000	Massachusetts provider ignored request of personal representative seeking access to her father's PHI
Arbour Hospital	$65,000	Massachusetts mental health services provider kept patient waiting 5 months before granting access to his PHI
University of Cincinnati Medical Center, LLC	$65,000	Ohio academic medical center failed to respond to patient's request to send an electronic copy of her medical records maintained in its electronic health record (EHR) to her lawyers

Provider	Settlement Amount*	Allegations
Housing Works Inc.	$38,000	New York City non-profit services provider refused patient's request for a copy of his medical records
Peter Wrobel, M.D., P.C., dba Elite Primary Care	$36,000	Georgia primary care practice failed to provide patient access to his medical records
Village Plastic Surgery	$30,000	New Jersey practice failed to provide patient timely access to his medical records
Riverside Psychiatric Medical Group	$25,000	California medical group didn't provide patient copy of her medical records despite repeated requests and OCR intervention
Dr. Rajendra Bhayani	$15,000	NY physician didn't provide patient her medical records even after OCR intervened and closed the complaint
All Inclusive Medical Services, Inc.	$15,000	California multi-specialty family medicine clinic refused patient's requests to inspect and receive a copy of her records
Wise Psychiatry, PC	$10,000	Colorado psychiatric firm refused to provide personal representative access to his minor son's medical record
Diabetes, Endocrinology & Lipidology Center, Inc.	$5,000	West Virginia diabetes clinic made the mother of a minor patient wait nearly 2 years for access to his medical records
King MD	$3,500	Virginia psychiatric practice didn't provide patient access to her medical records even after OCR intervened, provided technical assistance and closed the complaint

*In addition to the monetary settlement, each accused provider had to agree to implement a corrective action plan and allow the OCR to conduct close monitoring for one to two years

PAMA Reporting Alert: New Rules for CDLTs that Aren't ADLTs Take Effect Jan. 1

Be aware of the new reporting requirements that apply for the next PAMA data reporting period starting in January 2022. **Explanation:** Section 3718 of the *Coronavirus Aid, Relief and Economic Security* (CARES)

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PAMA Reporting Alert: New Rules for CDLTs that Aren't ADLTs Take Effect Jan. 1, *from page 9*

Act revises the Clinical Laboratory Fee Schedule (CLFS) requirements for clinical diagnostic laboratory tests (CDLTs) that aren't considered advanced diagnostic laboratory tests (ADLTs). The CARES Act also revises the phase-in of payment reductions under the Medicare private payor rate-based CLFS.

The 3 PAMA Changes

There are three basic changes you need to know about:

1. The next data reporting period for CDLTs that aren't ADLTs will be Jan. 1, 2022 through March 31, 2022, and will be based on the original data collection period of Jan. 1, 2019 through June 30, 2019;
2. After this data reporting period, the three-year data reporting cycle for CDLTs that aren't ADLTs will resume, i.e., 2025, 2028, 2031, etc.; and
3. The statutory phase-in of payment reductions resulting from the private payor rate implementation is extended by an additional year, i.e., through CY 2024. There's a 0.0 percent reduction for CY 2021, and payment may not be reduced by more than 15 percent for CYs 2022 through 2024, as compared to the prior year.

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a Government-directed investigation and civil or administrative litigation."

The OIG has modified the SDP several times over the years in an effort to make it clearer and more attractive to providers, most notably in April 2013 when the agency added substantial new guidance on how to assemble the content included in disclosures and transparency into the process the agency uses to resolve matters disclosed.

The 6 Key SDP Changes

While less impactful than the 2013 changes, the new 2021 revisions include a number of significant provisions. Specifically, there are six changes lab compliance managers need to be aware of when deciding whether to pursue self-disclosure through the SDP:

1. Minimum Settlement Amounts Doubled

To keep up with increases to the maximum civil monetary penalty (CMP) amounts imposed in 2018, the OIG has doubled the minimum settlement amounts required to resolve matters using the SDP:

- From $50,000 to $100,000 for kickback related matters; and
- From $10,000 to $20,000 for all other matters.

Bottom Line: Don't rely on the SDP if the potential fraud you uncover involves an amount less than the new minimums.

2. New Requirement to Itemize Damages

While labs will still have to provide an estimate of damages, the new SDP requires the estimate to include an itemization of damages for each federal health care program, e.g., Medicare, Medicaid, TRICARE, etc., as well as a sum total estimate of damages for all programs.

3. Self-Disclosure for Grants & Contractors

The revised SDP clarifies that the SDP shouldn't be used for disclosures related to recipients of HHS grants, or for federal contractors. Instead, those matters should be disclosed via OIG's Grant Self-Disclosure Program and OIG's Contractor Self-Disclosure Program.

4. Disclosing Parties under Corporate Integrity Agreements

As before, organizations that are currently under Corporate Integrity Agreements (CIAs) are allowed to use the SDP. But from now on, the discloser must "reference the fact that the disclosing party is subject to a CIA" and "send a copy of the disclosure to the disclosing party's OIG monitor." The new SDP also clarifies that any disclosure that constitutes a "reportable event" under the CIA must be reported to OIG.

5. Interface between OIG & Department of Justice (DOJ)

Previous SDP: OIG stated that it would coordinate with the DOJ and "advocate that the disclosing parties receive a benefit from disclosure under the SDP" in **both** civil and criminal matters.

Revised SDP: OIG states that it will still advocate for a benefit in civil matters, but removes the same language with respect to criminal matters. OIG also notes that it will refer any disclosure of criminal conduct via the SDP to DOJ for resolution.

Bottom Line: Don't expect expect OIG to "help with" DOJ in criminal matters, regardless of how cooperative your lab is with the agency under the SDP.

6. Online Submission Required

The previous version of the SDP allowed for disclosure online or via mail. But OIG has eliminated mail disclosure and is requiring all disclosure to be submitted electronically through the OIG web page.

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Takeaway

You should automatically consider the SDP option any time you uncover what might turn out to be potential health care fraud at your lab. However, you need to adjust your pros and cons calculations to account for the new revisions. Among the changes, the one most likely to have a direct impact on the decision is the elimination of the expectation of OIG help with the DOJ on criminal matters. However, keep in mind that sentencing guidelines for criminal cases continue to award "credit" for compliance and disclosure efforts.

SELF-DISCLOSURE BY THE NUMBERS

In addition to announcing the rule changes, OIG provided updated historical statistics on the SDP process. Key numbers:

+2,200: The number of disclosures OIG has resolved under the SDP between 1998 and 2020

+$870 million: The amount recovered for federal health care programs as a result of those disclosures

330: The number of SDP cases OIG resolved through settlements resulting in the release of all disclosing parties from permissive exclusion without requiring any integrity measures between 2016 and 2020