

Regulatory Update

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Today's Topics

- 2020 Physician Fee Schedule.
- Proposed AKS and Stark Regulations.
- 2020 OPPS Rule.
- Hospital Price Transparency Rule.
- 2020 IPPS Rule.

2020 Physician Fee Schedule

- This year's themes:
 - Responding to the opioid epidemic.
 - Reducing administrative burdens.
 - Modernizing scope of practice.
- Miscellaneous FYIs.

New Medicare Part B Benefit

- Opioid Use Disorder (OUD) treatment services furnished by an Opioid Treatment program (OTP).
 - New benefit pursuant to SUPPORT Act.
 - Covered services listed at 42 CFR § 410.67(b).
 - OTP requirements listed at 42 CFR § 410.67(c).

Opioid Treatment Programs (cont'd)

- **Payments to OTPs are Bundled.**
 - Methodology for determining bundled payment rates for OUD treatment at 42 CFR § 410.67(d).
 - Bundle covers OUD treatment services that are furnished by the OTP to an individual during an “episode of care.”
- **OTP Site of Service (Telecommunications).**
 - CMS authorized certain OUD services furnished by OTPs to be provided via telehealth. 42 CFR § 410.67(b).
 - Beneficiaries can receive services from home.

Payment for Telehealth Services

- CMS added 3 new HCPCS G codes covering treatment for OUD.
 - HCPCS code G2086.
 - HCPCS code G2087.
 - HCPCS code G2088.
- No public requests to add services (February 10 deadline each year).

Medicare Enrollment of Opioid Treatment Programs

- Opioid Treatment Program (OTP) enrollment requires:
 - Current, valid accreditation by an accrediting body or other entity approved by SAMHSA.
 - Current, valid certification by SAMHSA.
 - CMS-855 (new category: OTP).
 - Provider Agreement.

New Enrollment Revocation Reason – Not Limited to OTP

New Sections 424.535(a)(22) and 424.530(a)(15):
Permits CMS to revoke or deny, a physician's or other eligible provider's enrollment if he or she has been subject to prior action from a state oversight board, federal or state health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program **if the underlying facts reflect improper professional conduct that led to patient harm.**

Review and Verification of Medical Record Documentation

- CMS wants to add flexibility by expressly allowing certain individuals to review and verify (sign/date) notes added to the medical record rather than requiring re-documentation.
- Applies to physicians, PAs, NPs, CNSs, CNMs and CRNAs. (42 CFR § § 410.20, 410.69, 410.74, 410.75, 410.76, and 410.77).
 - Original notes can be made by physicians; residents; nurses; medical, PA, and APRN students; or other members of the medical team.

Updates to the Quality Payment Program

Coming in 2021:

- CMS will begin to transition MIPS to the MIPS Value Pathways (MVP) framework.

Medicare Shared Savings Program Quality Measures

- Finalized set of 23 quality measures for ACOs.
- Alignment with MIPS may be on the horizon.

Ambulance Fee Schedule – New: Medicare Ground Ambulance Data Collection System

- CMS will sample 25% of all ground ambulance organizations for each of the four years of data collection.
- The data tool will collect information on service areas, response time, number of responses, level of services provided, cost of facilities, cost of vehicles, etc.
- Big Penalty! Failure to participate = 10% reduction in Medicare payments.

Deferring to State Scope of Practice Requirements

- ASCs: Nurse anesthetists may perform the pre-surgical anesthesia risk evaluation.
- Hospice: If a PA is designated as the patient's attending physician, the hospice may accept drug orders from that PA.

Physician Supervision for Physician Assistant (PA) Services

- Currently physicians must provide “general” supervision of PA.
- Commenters wanted PAs to be treated like NPs and CNSs.
- CMS agreed that the change would reduce burdens on PA practice, expand access to care, and bring Medicare up to date with current PA practice.

Physician Supervision for Physician Assistant (PA) Services

42 CFR § 410.74(a)(2)(iv) Physician assistants' services

(iv) Performs the services in accordance with state law and state scope of practice rules for physician assistants in the state in which the physician assistant's professional services are furnished. Any state laws and scope of practice rules that describe the required practice relationship between physicians and physician assistants, including explicit supervisory or collaborative practice requirements, describe a form of supervision for purposes of section 1861(s)(2)(K)(i) of the Act. For states with no **explicit state law and scope of practice rules** regarding physician supervision of physician assistant's services, physician supervision is a process in which a physician assistant has a working relationship with one or more physicians to supervise the delivery of their health care services. Such physician supervision is evidenced by documenting **at the practice level** the physician assistant's scope of practice and the working relationships the physician assistant has with the supervising physician/s when furnishing professional services.

Additional Updates

- Coinsurance for colorectal cancer screening tests.
- Opportunities for bundled payments.
- No CMS-prescribed form of Physician Certification Statement for covered non-emergency ambulance transportation.

Open Payments

- “Covered recipient” in § 403.902 will now include PAs, NPs, CNSs, CRNAs and CNMs.
- Modifies payment categories to include debt forgiveness, long-term medical supply or device loan, and acquisitions.
- Finalized a requirement that applicable manufacturers and group purchasing organizations provide the device identifiers to identify reported devices.

Office Based E/M Services

- Discussion starts at p. 62847.
- Changes take effect 1/1/21.
- Scrapped single payment rate for levels 2-4.
- For office only, dramatic change to code Selection.
 - Time.
 - Medical decision making.
 - No more bullets in the office!
- Can't use 1995 or 1997 Guidelines.

E/M Services

- Apparently they believe in the paradox of choice.

E/M Services

- Apparently they don't believe in the pair of docs having choice?

E/M Services

- Clinic time may now include coordination of care even if it is not face-to-face.
- Prolonged office codes. 55, 70 and 85 minutes for established patients, 75, 90 and 105 for new.
- Time must be within the calendar day.
- Some “interesting” comments about split/shared.

TABLE 34: RUC-Recommended Pre-, Intra-, Post-Service Times, RUC-Recommended Total Times for CPT codes 99202-99215 and Actual Total Time

HCPCS	Pre-Service Time	Intra-Service Time	Immediate Post-Service Time	Actual Total Time	RUC-recommended Total Time
99202	2	15	3	20	22
99203	5	25	5	35	40
99204	10	40	10	60	60
99205	14	59	15	88	85
99211		5	2	7	7
99212	2	11	3	16	18
99213	5	20	5	30	30
99214	7	30	10	47	49
99215	10	45	15	70	70

Stark: Annual Update to the List of CPT/HCPCS Codes

TABLE 67: Additions to the Physician Self-Referral List of CPT¹/HCPCS Codes

CLINICAL LABORATORY SERVICES
{No additions}
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES
90912 Bfb training 1* 15 min
90913 Bfb training ea addl 15 min
97129 Ther ivntj 1* 15 min
97130 Ther ivntj ea addl 15 min
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES
0558T Ct scan f/biomchn ct alys
74221 X-ray xm esophagus 2ctrst
74248 X-ray sm int f-thru std
74251 X-ray xm sm int 2ctrst std
74270 X-ray xm colon 1ctrst std
74280 X-ray xm colon 2ctrst std
78429 Myocrd img pet 1 std w/ct
78430 Myocrd img pet rst/sts w/ct
78431 Myocrd img pet rst & sts ct
78432 Myocrd img pet 2rtracer
78433 Myocrd img pet 2rtracer ct
78434 Aqmbf pet rest & rx stress
93356 Myocrd strain img spckl trk
RADIATION THERAPY SERVICES AND SUPPLIES
A9590 Iodine i-131 iobenguane 1mci
64625 Rf abltj nrv nrvtg si jt
78830 Rp loclzj tum spect w/ct 1
78831 Rp loclzj tum spect 2 areas
78832 Rp loclzj tum spect w/ct 2
78835 Rp quan meas single area
DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
{No additions}
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES
90694 Vacc acc allV4 no prsrv 0.5ml im

¹CPT codes and descriptions only are copyright 2019 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

TABLE 68: Deletions from the Physician Self-Referral List of CPT¹/HCPCS Codes

CLINICAL LABORATORY SERVICES
0357T Cryopreservation oocyte(s)
0020U Rx test prsmv ur w/def conf
0028U Cyp2d6 gene cpy nmr cmn vmt
0057U Onc sld org neo mma 51 gene
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES
90911 Biofeedback peri/uro/rectal
95831 Limb muscle testing manual
95832 Hand muscle testing manual
95833 Body muscle testing manual
95834 Body muscle testing manual
G0460 Autologous PRP for ulcers
G0515 Cognitive skills development
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES
74241 X-ray exam upper gi tract
74245 X-ray exam upper gi tract
74247 Contrast x-ray upper gi tract
74249 Contrast x-ray upper gi tract
78205 Liver imaging (3D)
78206 Liver image (3d) with flow
78320 Bone imaging (3D)
78607 Brain imaging (3D)
78647 Cerebrospinal fluid scan
78710 Kidney imaging (3D)
78805 Abscess imaging ltd area
78806 Abscess imaging whole body
78807 Nuclear localization/abscess
93965 Extremity study
RADIATION THERAPY SERVICES AND SUPPLIES
{No deletions}
DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
{No deletions}
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES
{No deletions}

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Updated DHS Code list is available here:

https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes

Proposed Anti-Kickback Safe Harbors

- <https://www.federalregister.gov/documents/2019/10/17/2019-22027/medicare-and-state-healthcare-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the>
- 84 FR 55694, published 10/17/19.
- Only PROPOSED.
- Comments due 12/31/19.

Proposed Anti-Kickback Safe Harbors

- Proposes tweaks to the personal services, warranties, electronic health records, safe harbors and creates new safe harbors for care coordination and value-based purchasing.
- No requirement to meet a safe harbor.
- Intent is everything.

Proposed Stark Changes

- <https://www.federalregister.gov/documents/2019/10/17/2019-22028/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations>
- 84 FR 55766, published 10/17/19.
- Only proposed, but...
- Comments due 12/31/19.

Proposed Stark Changes

- Significant changes to definitions, including commercially reasonable, fair market value, general market value, value-based activity and more.
- Some of these aren't fully baked. (Would it be confusing to use "entity" in two different ways??).
- Would change comp. formula exceptions, including the ability to give credit for "DHS" for non-Medicare/caid patients.

Proposed Stark Changes

- Important changes to the definition of “takes into account.”
- Compensation “takes into account” referrals if “compensation includes the physician’s referrals to the entity as a variable, resulting in an increase or decrease in the physician’s (or immediate family member’s) compensation that positively correlates with the number or value of referrals” (underlining in original).

84 FR 55793

Proposed Stark Changes

- Focus on the word “variable.” A variable is part of a mathematical formula.
- Consider the difference between a compensation formula that says “if you have 5 years of experience your hourly rate is 1.2 times higher” and “we often pay more for experienced workers.”
- Rejects the reasoning of *United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.* See 84 FR 55795.

Proposed Stark Changes

However, for clarity, we reaffirm the position we took in the Phase II regulation. With respect to employed physicians, a productivity bonus will not take into account the volume or value of the physician's referrals solely because corresponding hospital services (that is, designated health services) are billed each time the employed physician personally performs a service. We are also clarifying that our guidance extends to compensation arrangements that do not rely on the exception for bona fide employment relationships at § 411.357(c), and under which a physician is paid using a unit-based compensation formula for his or her personally performed services, provided that the compensation meets the conditions in the special rule at § 411.354(d)(2). That is, under a personal service arrangement, an entity may compensate a physician for his or her personally performed services using a unit-based compensation formula— even when the entity bills for designated health services that correspond to such personally performed services—and the compensation will not take into account the volume or value of the physician's referrals if the compensation meets the conditions of the special rule at § 411.354(d)(2) (see 69 FR 16067). Page 55795

OPPS Rule

- Final rule published in the Federal Register on 11/12/2019, 84 FR 61142.
- <https://www.federalregister.gov/documents/2019/11/12/2019-24138/medicare-program-changes-to-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center>

OPPS Highlights

- Some highlights:
 - Overall increase of \$6.3 billion.
 - Procedures removed from IPO.
 - Lowered supervision requirement for hospital outpatient therapeutic services.
 - Prior authorization requirement for certain procedures.
 - Continuation of site-neutral payment policy.
 - Continuation of policy of decreased 340B reimbursement.

Inpatient Only List

- IPO procedures are not reimbursable under the OPPS.
- Over time, some procedures have been moved off the IPO list.
- CMS has established a 5-factor test for removal from the list.

Inpatient Only List

- Several procedures have been removed from the IPO list:
 - Total hip arthroplasty and associated anesthesia.
 - Six spine procedures and associated anesthesia.
- List of CPT codes at 84 FR 61359.

Inpatient Only List

- CMS emphasizes that inpatient admission may still be necessary for these procedures, to be determined on a case-by-case basis.
- These inpatient admissions are subject to the 2-midnight rule.

Inpatient Only List

- However, procedures removed from the IPO list will be exempt from site of service claim denials, eligibility for BFCC-QIC referrals to RACs for noncompliance with the 2-midnight rule, and RAC reviews for patient status for a period of two years.

84 FR 61364

Supervision Requirement

- Prior to the 2020, 42 C.F.R. § 410.27 required “direct supervision” for most hospital outpatient therapy services.
- This rule amends the regulation to require, at a minimum, “general supervision.”

Direct Supervision

“[D]irect supervision” means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed.

42 C.F.R. § 410.27(a)(1)(iv)(A) (2019)

General Supervision

“General supervision” means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.

42 C.F.R. § 410.32(b)(3)(i)

Rationale

- Since 2010, CMS did not enforce the direct supervision requirement for small rural hospitals and CAHs due to staffing shortages for these provider types.
- This created a “two-tiered system” of physician supervision.

Rationale for the Change

“[W]e have not learned of any data or information from CAHs or small rural hospitals indicating that the quality of outpatient therapeutic services has been affected by requiring only general supervision for these services.”

84 FR 61360

Caveats

- State scope of practice and supervision requirements still apply.
- CoPs make medical staff responsible for quality of services.
- Pulmonary rehab, cardiac rehab and intensive cardiac rehab still require direct supervision by a physician.

Prior Authorization Requirement

- CMS noted “significant increases” in the utilization of some OPD services.
- CMS is targeting services that are likely to be cosmetic and therefore not covered by Medicare.
 - Blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty and vein ablation.

Prior Authorization Requirement

- Claims statutory authority for change under its authority to create “method[s] for controlling unnecessary increases in the volume of covered outpatient services.”
 - We’ll come back to this...
- No parallel process for the ASC PPS.

42 C.F.R. § 419.82

- Process managed by MACs.
- Prior auth is a condition of payment.
- Prior auth request must include all documentation necessary to show service meets coverage, coding and payment rules.
- Provisional decision issued within 10 business days.
- Claim might still be denied.

42 C.F.R. § 419.83(c)

- CMS may “exempt” a provider from the prior auth process “upon provider’s demonstration of compliance” with the coding, coverage and payment rules.
- Demonstration must occur through the prior auth process.

Site-Neutral Payment Policy

- For several years, there has been a focus on narrowing the availability of Part A-level payment for off-campus PBDs.
- Bipartisan Budget Act of 2015 removed off-campus PBDs from the OPPS, grandfathering existing off-campus PBDs.

Site-Neutral Payment Policy

- Last year's rule began a two-year phase in to move reimbursement for most off campus PBDs paid on the OPPS to PFS levels.
 - 2019: paid at 70% of OPPS.
 - 2020: paid at 40% of OPPS.

AHA v. Azar

- AHA challenged this cut in federal court arguing that CMS lacked statutory authority for the adjustment.
 - AHA argues that rule is impermissible because it is not budget neutral, a requirement of the Social Security Act.
 - CMS claims that it can make non-neutral changes to “control[] unnecessary increases in volume.”

AHA v. Azar

- Court conducted a detailed analysis of the statutes and concluded that CMS had violated the statute.
- Court vacated the 2019 rule and remanded to the agency “for further action consistent with the correct legal standard.”

AHA v. Azar, Civil Action No. 18-2841 (RMC)
(D.D.C. September 17, 2019)

CMS's Response to AHA v. Azar

- CMS acknowledged that the 2019 rule was vacated and stated that it is “working to ensure affected 2019 claims for clinic visits are paid consistent with the court’s order.”
- CMS is moving forward with the cut in 2020.

CMS's Response to AHA v. Azar

“For CY 2020, CMS, will be going forward with the phase-in. We respectfully disagree with the district court and continue to believe the Secretary has the authority to address unnecessary increases in the volume of outpatient services. CMS is still considering how we would remedy hospitals if we either do not appeal this ruling or do not succeed on appeal if one is so authorized.”

84 FR 61368

340B Cuts

- Drug discount program for certain providers (“covered entities”).
- Prior to 2018, CEs were reimbursed for 340B drugs at average sale price (“ASP”) plus 6%.
- 2018 OPSS reduced 340B reimbursement to ASP minus 22.5%.

AHA v. Azar

- AHA sued, arguing that CMS violated the statute which requires CMS to set reimbursement rates at ASP + 6% or to set other rates based on hospital acquisition data (CMS has not collected or used this data).
- CMS argued that its statutory authority to “calculat[e] and adjust[.]” rates empowered the agency to cut rates by almost 30%.

AHA v. Azar

- Court sided with the AHA on 2018 and 2019 340B rates.
- The Court remanded the rule to CMS because vacating it would be “highly disruptive.”
- At the government’s request, the Court entered judgment to allow an immediate appeal.
- Appeal was argued 11/8/2019.

AHA v. Azar, Civil Action No. 18.2084 (RC)
(D.D.C. Orders dated December 27, 2018, May 6, 2019, July 10, 2019)

CMS's Response to AHA v. Azar

- CMS is continuing its policy of reimbursing 340B drugs at ASP minus 22.5% in 2020.
- CMS will collect hospital acquisition cost data, which may be used to fashion a remedy for 2018 and 2019 rates.

Pricing Transparency

- <https://www.federalregister.gov/documents/2019/11/27/2019-24931/medicare-and-medicare-programs-cy-2020-hospital-outpatient-pps-policy-changes-and-payment-rates-and>
- 84 FR 62568, published 11/15/19.
- Effective 1/1/21.
- Applies only to hospitals, but to all hospitals.

Key Terms

- *De-identified maximum (minimum) negotiated charge* means the highest (lowest) charge that a hospital has negotiated with all third party payers for an item or service.
- *Discounted cash price* means the charge that applies to an individual who pays cash (or cash equivalent) for a hospital item or service.

Key Terms

- *Gross charge* means the charge for an individual item or service that is reflected on a hospital's chargemaster, absent any discounts.
- *Machine-readable format* means a digital representation of data or information in a file that can be imported or read into a computer system for further processing. Examples of machine-readable formats include, but are not limited to, .XML, .JSON and .CSV formats.

Key Terms

- *Shoppable service* means a service that can be scheduled by a healthcare consumer in advance.

Key Terms

- *Standard charge* means the regular rate established by the hospital for an item or service provided to a specific group of paying patients. This includes all of the following as defined under this section:
 - (1) *Gross charge.*
 - (2) *Payer-specific negotiated charge.*
 - (3) *De-identified minimum negotiated charge.*
 - (4) *De-identified maximum negotiated charge.*
 - (5) *Discounted cash price.*

Subpart B – Public Disclosure Requirements

§ 180.40 General requirements.

A hospital must make public the following:

- a) A machine-readable file containing a list of all standard charges for all items and services as provided in § 180.50.
- b) A consumer-friendly list of standard charges for a limited set of shoppable services as provided in § 180.60.

How Will This Work?

- Two separate requirements: publishing “standard charges” and displaying “shoppable services.” In lieu of a list of shoppable services, hospital may use an internet based price estimating tool for 70 specified shoppable services and at least 230 additional shoppable services.
- Must be prominently displayed on the website, accessible to the public without charge or registration.

How Will This Work?

- The list for all service must include:
 - Gross charge for inpatient and outpatient care.
 - Payer specific negotiated charge for each payer.
 - De-identified maximum and minimum negotiated charges.
 - The discounted case price.

Is This Going to Happen?

- Hospitals filed suit 12/4 to stop the implementation.
- Key arguments: exceeds statutory authority, violates 1st Amendment by compelling speech that doesn't directly and materially advance a state interest, arbitrary and capricious.

Authority: 42 U.S.C § 300gg-18(e)

(e) Standard hospital charges — Each hospital operating within the United States shall for each year establish (and update) and make public (in accordance with guidelines developed by the Secretary) a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1395ww(d)(4) of this title.

IPPS Rule

- Final rule published in the Federal Register on 8/16/2019, 84 FR 42044.
- <https://www.federalregister.gov/documents/2019/08/16/2019-16762/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the>

IPPS Rule

- Some highlights:
 - Overall increase of \$3.8 billion.
 - Modifications to the wage index intended to reduce disparities for low-wage (often rural) hospitals.
 - Increased payments under the New Technology Add-On Payment program.
 - Tweaks to a number of quality and reporting programs.

Questions?

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