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PARAREV

Colonoscopy Coding

Modifiers, E/M Coding And Medical Necessity

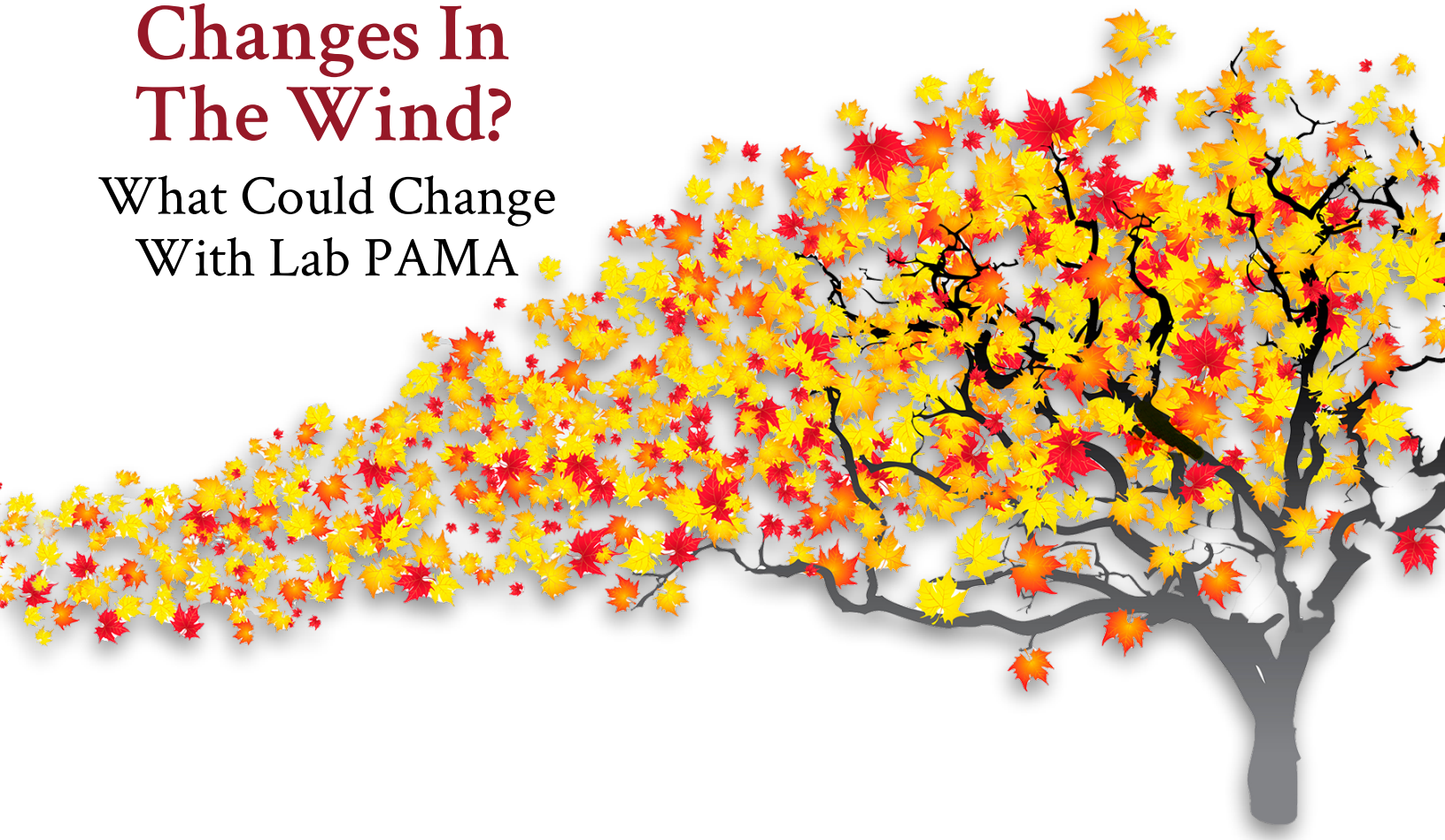
Losing Millions?

Inaccurate Medicare Transfer DRG Reductions

SPECIAL UPDATE

Changes In The Wind?

What Could Change With Lab PAMA



MEDICARE RULE REGARDING COLONOSCOPIES

Q. We have been working with our coders to better help them understand modifiers XS and XU. When reporting two or more diagnostic colonoscopy codes, is it appropriate to append modifier XS (separate structure), or should we report modifier XU (unusual, non-overlapping service)? For example, we need to append a modifier to report 45380 with 45385 to resolve a CCI edit.

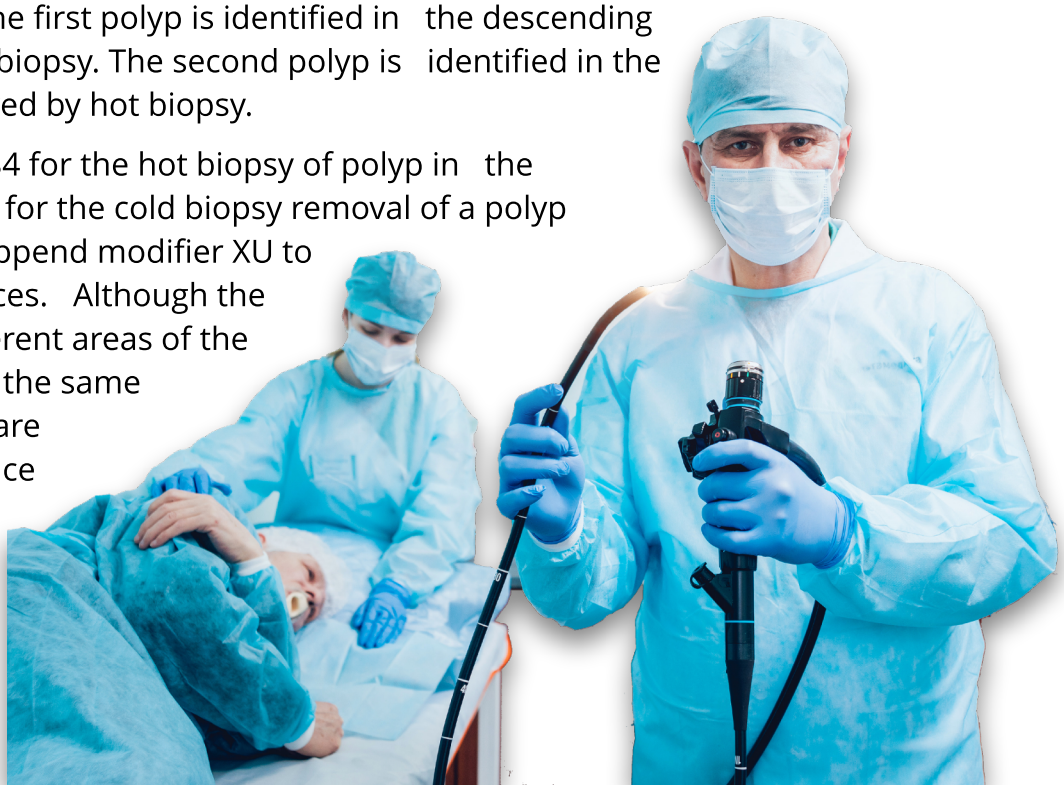
A. The modifier assignment will be dependent on the site of the polyp being removed. If all polyps removed are in the large intestine and each removed by a different method (i.e., cold biopsy, hot biopsy, snare), append modifier XU. The large intestine starts at the sigmoid colon and ends at the cecum.

This is considered one anatomic site.

Consider these two scenarios.

Scenario 1:
The patient presents for a colonoscopy. The scope is advanced to the cecum. During the exam two polyps are identified. The first polyp is identified in the descending colon and removed by cold biopsy. The second polyp is identified in the transverse colon and removed by hot biopsy.

In this scenario, report 45384 for the hot biopsy of polyp in the transverse colon and 45380 for the cold biopsy removal of a polyp in the descending colon. Append modifier XU to 45380 for overlapping services. Although the polyps are identified at different areas of the large intestine, they were in the same anatomic site. The services are considered overlapping since the polyps were removed in different methods (i.e., cold biopsy and hot biopsy).



MEDICARE RULE REGARDING COLONOSCOPIES

Scenario 2:
The patient presents for a colonoscopy. The scope is advanced to the cecum. During the exam two polyps are identified. The first polyp is identified in the rectum and removed by cold biopsy. The second polyp is identified in the transverse colon and removed by hot biopsy.In this scenario, report 45384 for the hot biopsy of polyp in the transverse colon and 45380 for the cold biopsy removal of a polyp in the rectum. Append modifier XS to 45380 for separate anatomic site. One polyp was identified in the large intestine and the other polyp was in the rectum. Since the rectum is a different anatomic site from the large intestine, XS is appropriate.

Q. We have been holding bills at our Rural Health Clinic for pre-operative clearance visits for Medicare patients scheduled for a colonoscopy. I have been asked to investigate whether these encounters are billable. We have heard that E/Ms “before/prior to” a screening C-scope were not to be billed.

However, for the 16 years I have been in clinic billing we have always billed them if they weren’t the “day before or day of” of procedure, as those would get bundled. We’ve gotten paid just fine and in all those years to my knowledge, none of our MC audits resulted in any take backs or fines regarding our billing them.

We researched coding forums on-line as well, and any data I could find from or regarding MC and screening C-scopes and opinion, is divided. Many stated that the “before/prior to” means within 24 hours of the procedure; and that they have billed for them as a rule and always been paid (as we did). Others said they felt that the “before/prior to” meant any time, even weeks before, and they didn’t bill for them.

Is the “consulting/decision for surgery” visit to a specialist for a screening colonoscopy billable? We understand that a pre-operative clearance/H&P after the decision for surgery is made, is not billable as it is not deemed medically necessary.

But can we bill for the visit in which the patient meets the specialist, and a decision is made as to whether or a colonoscopy should be done or not?Also, if the consult/decision for surgery is indeed billable, does it fall into the “day before/day of “rule where it’s not billable even with modifier 57, due to being a minor procedure, or is that rule only regarding pre-ops?

Typically, our consults are done days to weeks prior to the scope, but sometimes it is more of a list-minute decision.

MEDICARE RULE REGARDING COLONOSCOPIES

A. Medicare and most other insurers cover only medically necessary services. A patient is eligible for a screening colonoscopy if there are no signs or symptoms of GI trouble. It stands to reason that a pre-op clearance exam that finds no health care condition to support the medical necessity of the visit is not medically necessary, and therefore should not be billed, regardless of the timing (same day or not.) Medicare may have paid claims for such visits at the RHC in the past, but that doesn't necessarily mean the visits have truly met the general test of medical necessity.

However, if there is a medically necessary reason for the visit, such as any other complicating condition that would be pertinent to the safety of the patient while undergoing the procedure (high blood pressure, diabetes, etc.), then the visit might be considered medically necessary. Medical necessity will be determined by the documentation and diagnosis coding provided in addition to the ICD10 Z01.81x (Encounter for preprocedural examinations.)
Medicare defines an RHC visit as "medically necessary".

10.1 - RHC General Information
(Rev. 3434, Issued: 12-31-15, Effective: 03-31-16, Implementation: 03-31-16)

RHCs are facilities that provide services that are typically furnished in an outpatient clinic setting. The statutory requirements that RHCs must meet to qualify for the Medicare benefit are in §1861(aa) (2) of the Social Security Act (the Act).

A RHC visit is defined as a medically-necessary, face-to-face (one-on-one) medical or mental health visit, or a qualified preventive health visit, with a RHC practitioner during which time one or more RHC services are rendered. A RHC practitioner is a physician, nurse practitioner (NP), physician assistant (PA), certified nurse midwife (CNM), clinical psychologist (CP), and clinical social worker (CSW). A Transitional Care Management (TCM) service can also be a RHC visit. A RHC visit can also be a visit between a home-bound patient and an RN or LPN under certain conditions.

The American Gastroenterological Association website also discusses this issue.

If the service is not a screening colonoscopy, then several other factors influence whether a pre-operative H&P visit should be separately reported and/or reimbursed:

- Whether the E/M is performed by the same physician/same group practice who will perform the surgical procedure, and
- Whether the decision for surgery has already been made at the time of the H&P; and
- Whether the E/M is performed on the same day or the day prior to the surgical procedure, and
- Whether the global period for the surgical procedure 10 days or less
- Whether the service was medically necessary, in other words, were there conditions that required assessment before the patient could safely have surgery;
- If the procedure is preventive in nature, and there is no "problem" to report on a problem-focused visit, then the visit does not meet medical necessity

MEDICARE RULE REGARDING COLONOSCOPIES

Another physician (not the surgeon) can bill for an H&P after the surgeon makes the decision to perform surgery, and refers the patient to a second physician (often a primary care physician) for a preoperative H&P.

This service is reportable, but if the visit is not deemed to be medically necessary, a payer may deny payment. Medical necessity will be determined by the documentation and diagnosis coding provided in addition to the ICD10 Z01.81x:

ICD-10 Codes
Codes and/or Descriptions: Z0181

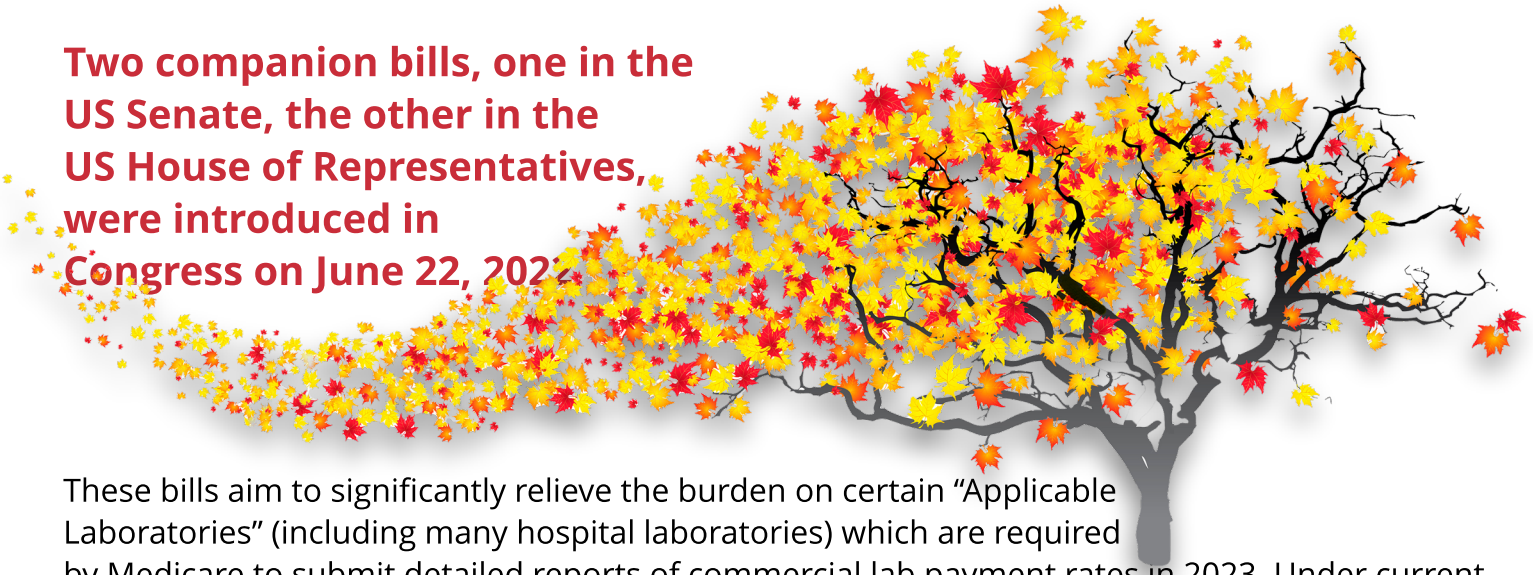
ICD-10 Code	Description
Z0181	Encounter for preprocedural examinations
Z01810	Encounter for preprocedural cardiovascular examination
Z01811	Encounter for preprocedural respiratory examination
Z01812	Encounter for preprocedural laboratory examination
Z01818	Encounter for other preprocedural examination

The following matrix was created to help simplify the various scenarios when a medically necessary pre-op exam would be billable.

	Date of Pre-Op E/M		
	More than one day prior to surgery	Within one day of surgery with a Global Period of >= 10 days	Within one day of surgery with a Global Period of < 10 days
E/M performed by the same physician who will perform the surgery	Billable	Not billable	Billable only if Decision for Surgery made (modifier 57)
E/M performed by another (non-surgeon) provider	Billable	Billable	Billable

CHANGES IN THE WIND? PROPOSED LEGISLATION MAY CHANGE PAMA RULES

Two companion bills, one in the US Senate, the other in the US House of Representatives, were introduced in Congress on June 22, 2022.



These bills aim to significantly relieve the burden on certain "Applicable Laboratories" (including many hospital laboratories) which are required by Medicare to submit detailed reports of commercial lab payment rates in 2023. Under current regulations, "Applicable laboratories" must report the volume and rate of payments received for each lab test CPT®/HCPCS from commercial payers during a six-month period.

The reports are due every three years; the report deadline for the 2019 reporting period is due during the first quarter of 2023. However, the deadline has been repeatedly extended due to COVID, and the bills may revise altogether the reporting requirement. Medicare needs providers to report payment data in order to calculate the weighted median rate paid by commercial payers for each test, as required under the Protecting Access to Medicare Act (2014.)

The first attempt to collect that data in 2016 was arguably flawed, and resulted in significant cuts to reimbursement under the Clinical Laboratory Fee Schedule beginning in 2018. Although Medicare attempted to correct the flawed process by expanding the number and types of providers required to report data from 2019, "Applicable Laboratories" have complained that the process is burdensome. Congress has delayed the reporting deadline three times since the requirement was expanded to include many hospitals, and now Congress appears to be poised to change the requirement significantly.

The two companion bills would change the data collection method to a statistically representative process conducted every four years, rather than broad reporting responsibility every three years.

CHANGES IN THE WIND? PROPOSED LEGISLATION MAY CHANGE PAMA RULES

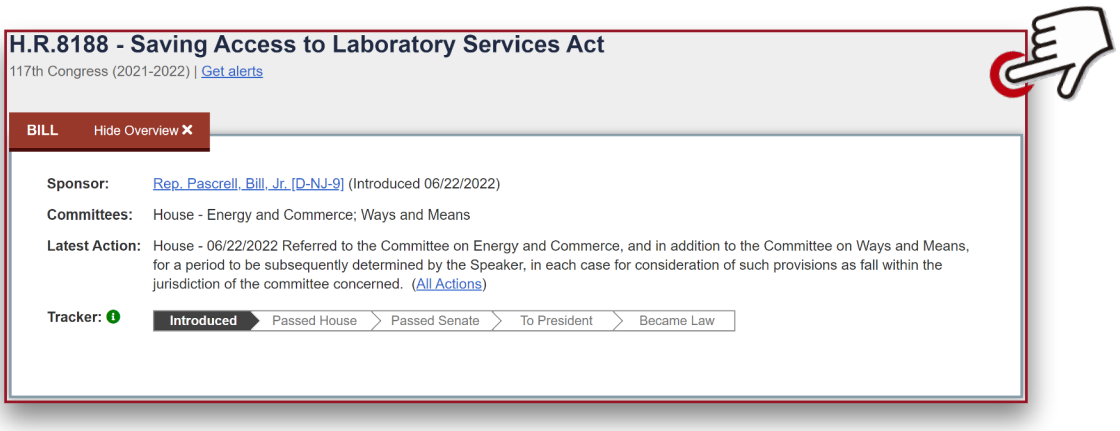
The bills are:

- **Senate Bill S.4449**– Saving Access to Laboratory Services Act, (SALSA); introduced by Sen. Richard Burr (R-NC), cosponsored by Senator Sherrod Brown (D-OH).Status: referred to the Senate Committee on Finance

https://www.congress.gov/bill/117th-congress/senate-bill/4449?s=1&r=5

- **House BillH.R.8188**- Saving Access to Laboratory Services Act, introduced by Rep. Bill Pascrell Jr., (D-NY), and cosponsored by two more Democrats and two Republican representatives.Status: referred to both the Committee on Energy and Commerce and to the Ways and Means Committee.

https://www.congress.gov/bill/117th-congress/house-bill/8188?s=5&r=553



So far, both bills appear to enjoy bipartisan support, and are supported by numerous organizations of providers, including:

- The American Clinical Lab Association
- The National Independent Lab Association
- The American Society for Clinical Laboratory Science
- William Morice II, M.D., president of Mayo Clinic Laboratories and Matt Sause, president and CEO of Roche Diagnostics North America, who wrote an editorial on the topic for RealClearPolicy.com.

Neither bill provides recognition or compensation to organizations which already invested significant time and money into preparing for the mandatory report for payments received in the first six months of 2019.Many providers who meet the "Applicable Laboratory" definition have been diligently preparing (or have already prepared) details of 2019 payments in order to avoid costly penalties for failure to meet the deadline.

ParaRev will continue to monitor progress on the bills and report back as actions are taken up in Congressional committees.

CHANGES IN THE WIND? PROPOSED LEGISLATION MAY CHANGE PAMA RULES

Here Is The Complete Text

§1395m–1. Improving policies for clinical diagnostic laboratory tests

(a) Reporting of private sector payment rates for establishment of medicare payment rates

(1) In general

(A) General reporting requirements

·~~Subject to subparagraph (B)~~Subject to subparagraph (B) and (C), beginning January 1, 2016, and every 3 years thereafter (or, annually, in the case of reporting with respect to an advanced diagnostic laboratory test, as defined in subsection (d)(5)), an applicable laboratory (as defined in paragraph (2)) shall report to the Secretary, at a time specified by the Secretary (referred to in this subsection as the "reporting period"), applicable information (as defined in paragraph (3)) for a data collection period (as defined in paragraph (4)) for each clinical diagnostic laboratory test that the laboratory furnishes during such period for which payment is made under this part.

(B) Revised reporting period

·In the case of reporting with respect to clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests, the Secretary shall revise the reporting period under subparagraph (A) such that-

(i) no reporting is required during the period beginning January 1, 2020, and ending~~December 31, 2022~~December 31, 2024;

(ii) reporting is required during the period~~beginning January 1, 2023, and ending March 31, 2023~~Beginning January 1, 2026 and ending March 31, 2026; and

(iii) reporting is required~~every three years~~every four yearsafter the period described in clause (ii).

(C)USE OF STATISTICAL SAMPLING FOR WIDELY AVAILABLE CLINICAL DIAGNOSTIC LABORATORY TESTS.—

"(i)IN GENERAL.—Subject to clause (ii), with respect to data collection periods for reporting periods beginning on or after January 1, 2026, in the case of a widely available clinical diagnostic laboratory test (as defined in clause (iii)), in lieu of requiring the reporting of applicable information from each applicable laboratory, the Secretary shall require the collection and reporting of applicable information from a statistically valid sample of applicable laboratories for each such widely available clinical diagnostic laboratory test.

"(ii)REQUIREMENTS FOR STATISTICAL SAMPLING.—"(I)IN GENERAL.—The Secretary, in consultation with stakeholders, shall develop a methodology for a statistically valid sample under clause (i), using the maximal brewer selection method, as described in the June 2021 Medicare Payment Access Commission Report to the Congress, to establish the payment amount for a widely available clinical diagnostic laboratory test under paragraph (2) of subsection (b) for each applicable HCPCS code for a widely available clinical diagnostic laboratory test.

CHANGES IN THE WIND? PROPOSED LEGISLATION MAY CHANGE PAMA RULES

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"(II) REPRESENTATIVE SAMPLING.—The methodology under subclause (I) for a statistically valid sample under clause (i) shall, for each applicable HCPCS code for a widely available clinical diagnostic laboratory test—

"(aa) provide for a sample that allows for the payment amounts established under paragraph (2) of subsection (b) for such a test to be representative of rates paid by private payors to applicable laboratories receiving payment under this section, including independent laboratories, hospital laboratories, hospital outreach laboratories, and physician office laboratories that furnish the widely available clinical diagnostic laboratory test;

"(bb) include applicable information (as defined in paragraph (3)) with respect to such widely available clinical diagnostic laboratory test from such different types of applicable laboratories; and

"(cc) be of sufficient size to accurately and proportionally represent the range of private payor payment rates received by each such type of applicable laboratory weighted according to the utilization rates of each type of applicable laboratory for the widely available clinical diagnostic laboratory test during the first 6 months of the calendar year immediately preceding the data collection period applicable to the sample to be collected.

"(III) LEAST BURDENSOME DATA COLLECTION AND REPORTING PROCESSES.—The methodology developed by the Secretary shall be designed to reduce administrative burdens of data collection and reporting on applicable laboratories and the Centers for Medicare & Medicaid Services to the greatest extent practicable.

"(IV)PUBLICATION OF LIST OF WIDELY AVAILABLE CLINICAL DIAGNOSTIC LABORATORY TESTS AND NOTIFICATION TO APPLICABLE LABORATORIES REQUIRED TO REPORT APPLICABLE INFORMATION.—Not later than September 30 of the year immediately preceding each data collection period (as defined in paragraph (4)), the Secretary shall publish in the Federal Register a list of widely available clinical diagnostic laboratory tests and shall directly notify applicable laboratories required to report applicable information under this subsection.

"(iii) DEFINITION OF WIDELY AVAILABLE CLINICAL DIAGNOSTIC LABORATORY TEST.—In this subparagraph, the term 'widely available clinical diagnostic laboratory test' means a clinical diagnostic laboratory test that meets both of the following criteria during the first 6 months of the calendar year immediately preceding the data collection period applicable to the sample to be collected:

CHANGES IN THE WIND? PROPOSED LEGISLATION MAY CHANGE PAMA RULES

Here Is The Complete Text

"(I)PAYMENT RATE.—The payment amount determined for the clinical diagnostic laboratory test under this section is less than $1,000 per test.

"(II)NUMBER OF LABORATORIES PERFORMING THE TEST.—The number of applicable laboratories receiving payments under this section for the clinical diagnostic laboratory test (as determined by the Secretary using the national provider identifier of the provider of services or supplier on the claim submitted for payment under this part for such test) exceeds 100.".

(2) Definition of applicable laboratory

In this section, the term "applicable laboratory" means a laboratory that, with respect to its revenues under this subchapter, a majority of such revenues are from this section,section 1395l(h) of this title, orsection 1395w–4 of this title. The Secretary may establish a low volume or low expenditure threshold for excluding a laboratory from the definition of applicable laboratory under this paragraph, as the Secretary determines appropriate.

(3) Applicable information defined

(A) In general

·In this section, subject to subparagraph (B), the term "applicable information" means, with respect to a laboratory test for a data collection period, the following:

(i) The payment rate (as determined in accordance with paragraph (5)) that was paid by each private payor for the test during the period.

(ii) The volume of such tests for each such payor for the period.

(B) Exception for certain contractual arrangements

·Such term shall not include information with respect to a laboratory test for which payment is made on a capitated basis or other similar payment basis during the data collection period.

(4) Data collection period defined

(A) In general

·Subject to subparagraph (B), in this section, the term "data collection period" means a period of time, such as a previous 12 month period, specified by the Secretary.

(B) Exception

·In the case of the reporting period described in paragraph (1)(B)(ii) with respect to clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests, the term "data collection period" means the period beginning January 1, 2019, and ending June 30, 2019.

(5) Treatment of discounts

The payment rate reported by a laboratory under this subsection shall reflect all discounts, rebates, coupons, and other price concessions, including those described insection 1395w–3a(c)(3) of this title.

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(6) Ensuring complete reporting

In the case where an applicable laboratory has more than one payment rate for the same payor for the same test or more than one payment rate for different payors for the same test, the applicable laboratory shall report each such payment rate and the volume for the test at each such rate under this subsection. Beginning with January 1, 2019, the Secretary may establish rules to aggregate reporting with respect to the situations described in the preceding sentence.

(7) Certification

An officer of the laboratory shall certify the accuracy and completeness of the information reported under this subsection.

(8) Private payor defined

In this section, the term "private payor" means the following:

·(A) A health insurance issuer and a group health plan (as such terms are defined insection 300gg–91 of this title).

·(B) A Medicare Advantage plan under part C.

·(C) A medicaid managed care organization (as defined insection 1396b(m) of this title).

(9) Civil money penalty

(A) In general

·If the Secretary determines that an applicable laboratory has failed to report or made a misrepresentation or omission in reporting information under this subsection with respect to a clinical diagnostic laboratory test, the Secretary may apply a civil money penalty in an amount of up to $10,000 per day for each failure to report or each such misrepresentation or omission.

(B) Application

·The provisions ofsection 1320a–7a of this title(other than subsections (a) and (b)) shall apply to a civil money penalty under this paragraph in the same manner as they apply to a civil money penalty or proceeding undersection 1320a–7a(a) of this title.

(10) Confidentiality of information

Notwithstanding any other provision of law, information disclosed by a laboratory under this subsection is confidential and shall not be disclosed by the Secretary or a Medicare contractor in a form that discloses the identity of a specific payor or laboratory, or prices charged or payments made to any such laboratory, except-

·(A) as the Secretary determines to be necessary to carry out this section;

·(B) to permit the Comptroller General to review the information provided;

·(C) to permit the Director of the Congressional Budget Office to review the information provided; and

Here Is The Complete Text

·(C) to permit the Director of the Congressional Budget Office to review the information provided; and

·(D) to permit the Medicare Payment Advisory Commission to review the information provided.

(11) Protection from public disclosure

A payor shall not be identified on information reported under this subsection. The name of an applicable laboratory under this subsection shall be exempt from disclosure undersection 552(b)(3) of title 5.

(12) Regulations

Not later than June 30, 2015, the Secretary shall establish through notice and comment rulemaking parameters for data collection under this subsection.

(b) Payment for clinical diagnostic laboratory tests

(1) Use of private payor rate information to determine medicare payment rates

(A) In general

·Subject to paragraph (3) and subsections (c) and (d), in the case of a clinical diagnostic laboratory test furnished on or after January 1, 2017, the payment amount under this section shall be equal to the weighted median determined for the test under paragraph (2) for the most recent data collection period.

(B) Application of payment amounts to hospital laboratories

·The payment amounts established under this section shall apply to a clinical diagnostic laboratory test furnished by a hospital laboratory if such test is paid for separately, and not as part of a bundled payment undersection 1395l(t) of this title.

(2) Calculation of weighted median

For each laboratory test with respect to which information is reported under subsection (a) for a data collection period, the Secretary shall calculate a weighted median for the test for the period, by arraying the distribution of all payment rates reported for the period for each test weighted by volume for each payor and each laboratory.

(3) Phase-in of reductions from private payor rate implementation

(A) In general

·Payment amounts determined under this subsection for a clinical diagnostic laboratory test for each of 2017 through 2025 shall not result in a reduction in payments for a clinical diagnostic laboratory test for the year of greater than the applicable percent (as defined in subparagraph (B)) of the amount of payment for the test for the preceding year.

(B) Applicable percent defined

·In this paragraph, the term "applicable percent" means-

(i) for each of 2017 through 2020, 10 percent;

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(B) Applicable percent defined

·In this paragraph, the term "applicable percent" means-

(i) for each of 2017 through 2020, 10 percent;

(ii) for each of 2021 and 2022, 0 percent; and

(iii) for each of 2023 through 2025, 15 percent.

(C) No application to new tests

·This paragraph shall not apply to payment amounts determined under this section for either of the following.

(i) A new test under subsection (c).

(ii) A new advanced diagnostic test1(as defined in subsection (d)(5)) under subsection (d).

(4) Application of market rates

(A) In general

·Subject to paragraph (3), once established for a year following a data collection period, the payment amounts under this subsection shall continue to apply until the year following the next data collection period.

(B) Other adjustments not applicable

·The payment amounts under this section shall not be subject to any adjustment (including any geographic adjustment, budget neutrality adjustment, annual update, or other adjustment).

(5) Sample collection fee

In the case of a sample collected from an individual in a skilled nursing facility or by a laboratory on behalf of a home health agency, the nominal fee that would otherwise apply undersection 1395l(h)(3)(A) of this titleshall be increased by $2.

(c) Payment for new tests that are not advanced diagnostic laboratory tests

(1) Payment during initial period

In the case of a clinical diagnostic laboratory test that is assigned a new or substantially revised HCPCS code on or after April 1, 2014, and which is not an advanced diagnostic laboratory test (as defined in subsection (d)(5)), during an initial period until payment rates under subsection (b) are established for the test, payment for the test shall be determined-

·(A) using cross-walking (as described in section 414.508(a) of title 42, Code of Federal Regulations, or any successor regulation) to the most appropriate existing test under the fee schedule under this section during that period; or(B) if no existing test is comparable to the new test, according to the gap filling process described in paragraph (2).

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(2) Gapfilling process described

The gapfilling process described in this paragraph shall take into account the following sources of information to determine gapfill amounts, if available:

·(A) Charges for the test and routine discounts to charges.

·(B) Resources required to perform the test.

·(C) Payment amounts determined by other payors.

·(D) Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant.

·(E) Other criteria the Secretary determines appropriate.

(3) Additional consideration

In determining the payment amount under crosswalking or gapfilling processes under this subsection, the Secretary shall consider recommendations from the panel established under subsection (f)(1).

(4) Explanation of payment rates

In the case of a clinical diagnostic laboratory test for which payment is made under this subsection, the Secretary shall make available to the public an explanation of the payment rate for the test, including an explanation of how the criteria described in paragraph (2) and paragraph (3) are applied.

(d) Payment for new advanced diagnostic laboratory tests

(1) Payment during initial period

(A) In general

·In the case of an advanced diagnostic laboratory test for which payment has not been made under the fee schedule undersection 1395l(h) of this titleprior to April 1, 2014, during an initial period of three quarters, the payment amount for the test for such period shall be based on the actual list charge for the laboratory test.

(B) Actual list charge

·For purposes of subparagraph (A), the term "actual list charge", with respect to a laboratory test furnished during such period, means the publicly available rate on the first day at which the test is available for purchase by a private payor.

(2) Special rule for timing of initial reporting

With respect to an advanced diagnostic laboratory test described in paragraph (1)(A), an applicable laboratory shall initially be required to report under subsection (a) not later than the last day of the second quarter of the initial period under such paragraph.

Here Is The Complete Text

(3) Application of market rates after initial period

Subject to paragraph (4), data reported under paragraph (2) shall be used to establish the payment amount for an advanced diagnostic laboratory test after the initial period under paragraph (1)(A) using the methodology described in subsection (b). Such payment amount shall continue to apply until the year following the next data collection period.

(4) Recoupment if actual list charge exceeds market rate

With respect to the initial period described in paragraph (1)(A), if, after such period, the Secretary determines that the payment amount for an advanced diagnostic laboratory test under paragraph (1)(A) that was applicable during the period was greater than 130 percent of the payment amount for the test established using the methodology described in subsection (b) that is applicable after such period, the Secretary shall recoup the difference between such payment amounts for tests furnished during such period.

(5) Advanced diagnostic laboratory test defined

In this subsection, the term "advanced diagnostic laboratory test" means a clinical diagnostic laboratory test covered under this part that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and meets one of the following criteria:

·(A) The test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result.

·(B) The test is cleared or approved by the Food and Drug Administration.

·(C) The test meets other similar criteria established by the Secretary.

(e) Coding

(1) Temporary codes for certain new tests

(A) In general

·The Secretary shall adopt temporary HCPCS codes to identify new advanced diagnostic laboratory tests (as defined in subsection (d)(5)) and new laboratory tests that are cleared or approved by the Food and Drug Administration.

(B) Duration

(i) In general

Subject to clause (ii), the temporary code shall be effective until a permanent HCPCS code is established (but not to exceed 2 years).

(ii) Exception

The Secretary may extend the temporary code or establish a permanent HCPCS code, as the Secretary determines appropriate.

Here Is The Complete Text

(2) Existing tests

Not later than January 1, 2016, for each existing advanced diagnostic laboratory test (as so defined) and each existing clinical diagnostic laboratory test that is cleared or approved by the Food and Drug Administration for which payment is made under this part as of April 1, 2014, if such test has not already been assigned a unique HCPCS code, the Secretary shall-

·(A) assign a unique HCPCS code for the test; and

·(B) publicly report the payment rate for the test.

(3) Establishment of unique identifier for certain tests

For purposes of tracking and monitoring, if a laboratory or a manufacturer requests a unique identifier for an advanced diagnostic laboratory test (as so defined) or a laboratory test that is cleared or approved by the Food and Drug Administration, the Secretary shall utilize a means to uniquely track such test through a mechanism such as a HCPCS code or modifier.

(f) Input from clinicians and technical experts

(1) In general

The Secretary shall consult with an expert outside advisory panel, established by the Secretary not later than July 1, 2015, composed of an appropriate selection of individuals with expertise, which may include molecular pathologists, researchers, and individuals with expertise in laboratory science or health economics, in issues related to clinical diagnostic laboratory tests, which may include the development, validation, performance, and application of such tests, to provide-

·(A) input on-

(i) the establishment of payment rates under this section for new clinical diagnostic laboratory tests, including whether to use crosswalking or gapfilling processes to determine payment for a specific new test; and

(ii) the factors used in determining coverage and payment processes for new clinical diagnostic laboratory tests; and

·(B) recommendations to the Secretary under this section.

(2) Compliance with FACA

The panel shall be subject to the Federal Advisory Committee Act (5 U.S.C. App.).

(3) Continuation of annual meeting

The Secretary shall continue to convene the annual meeting described insection 1395l(h)(8)(B)(iii) of this titleafter the implementation of this section for purposes of receiving comments and recommendations (and data on which the recommendations are based) as described in such section on the establishment of payment amounts under this section.

(g) Coverage

(1) Issuance of coverage policies

Here Is The Complete Text

(g) Coverage

(1) Issuance of coverage policies

(A) In general

·A medicare administrative contractor shall only issue a coverage policy with respect to a clinical diagnostic laboratory test in accordance with the process for making a local coverage determination (as defined insection 1395ff(f)(2)(B) of this title), including the appeals and review process for local coverage determinations under part 426 of title 42, Code of Federal Regulations (or successor regulations).

(B) No effect on national coverage determination process

·This paragraph shall not apply to the national coverage determination process (as defined insection 1395ff(f)(1)(B) of this title).

(C) Effective date

·This paragraph shall apply to coverage policies issued on or after January 1, 2015.

(2) Designation of one or more medicare administrative contractors for clinical diagnostic laboratory tests

The Secretary may designate one or more (not to exceed 4) medicare administrative contractors to either establish coverage policies or establish coverage policies and process claims for payment for clinical diagnostic laboratory tests, as determined appropriate by the Secretary.

(h) Implementation

(1) Implementation

There shall be no administrative or judicial review undersection 1395ff of this title,section 1395oo of this title, or otherwise, of the establishment of payment amounts under this section.

(2) Administration

Chapter 35 of title 44shall not apply to information collected under this section.

(3) Funding

For purposes of implementing this section, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund undersection 1395t of this title, to the Centers for Medicare & Medicaid Services Program Management Account, for each of fiscal years 2014 through 2018, $4,000,000, and for each of fiscal years 2019 through 2023, $3,000,000. Amounts transferred under the preceding sentence shall remain available until expended.

(i) Transitional rule

During the period beginning on April 1, 2014, and ending on December 31, 2016, with respect to advanced diagnostic laboratory tests under this part, the Secretary shall use the methodologies for pricing, coding, and coverage in effect on the day before April 1, 2014, which may include cross-walking or gap filling methods.

CHANGES IN THE WIND? PROPOSED LEGISLATION MAY CHANGE PAMA RULES

Here Is The Complete Text

(Aug. 14, 1935, ch. 531, title XVIII, §1834A, as addedPub. L. 113–93, title II, §216(a), Apr. 1, 2014, 128 Stat. 1053; amendedPub. L. 116–94, div. N, title I, §105(a), Dec. 20, 2019, 133 Stat. 3100;Pub. L. 116–136, div. A, title III, §3718, Mar. 27, 2020, 134 Stat. 425;Pub. L. 117–71, §4, Dec. 10, 2021, 135 Stat. 1507.)

Editorial Notes

References in Text

The Federal Advisory Committee Act, referred to in subsec. (f)(2), isPub. L. 92–463, Oct. 6, 1972, 86 Stat. 770, which is set out in the Appendix to Title 5, Government Organization and Employees.

Amendments

2021-Subsec. (a)(1)(B)(i). Pub. L. 117–71, §4(b)(1), substituted "December 31, 2022" for "December 31, 2021".

Subsec. (a)(1)(B)(ii). Pub. L. 117–71, §4(b)(2), substituted "January 1, 2023" for "January 1, 2022" and "March 31, 2023" for "March 31, 2022".

Subsec. (b)(3)(A). Pub. L. 117–71, §4(a)(1), substituted "through 2025" for "through 2024".

Subsec. (b)(3)(B)(ii). Pub. L. 117–71, §4(a)(2)(A), substituted "for each of 2021 and 2022" for "for 2021".

Subsec. (b)(3)(B)(iii). Pub. L. 117–71, §4(a)(2)(B), substituted "2023 through 2025" for "2022 through 2024".

2020-Subsec. (a)(1)(B)(i). Pub. L. 116–136, §3718(a)(1), substituted "December 31, 2021" for "December 31, 2020".

Subsec. (a)(1)(B)(ii). Pub. L. 116–136, §3718(a)(2), substituted "January 1, 2022" for "January 1, 2021" and "March 31, 2022" for "March 31, 2021".

Subsec. (b)(3)(A). Pub. L. 116–136, §3718(b)(1), substituted "through 2024" for "through 2023".

Subsec. (b)(3)(B). Pub. L. 116–136, §3718(b)(2), added cl. (ii), redesignated former cl. (ii) as (iii), and substituted "2022 through 2024" for "2021 through 2023" in cl. (iii).

2019-Subsec. (a)(1). Pub. L. 116–94, §105(a)(1)(A), designated existing provisions as subpar. (A) and inserted heading, substituted "Subject to subparagraph (B), beginning January 1, 2016" for "Beginning January 1, 2016", inserted "(referred to in this subsection as the 'reporting period')" after "at a time specified by the Secretary", and added subpar. (B).

Subsec. (a)(4). Pub. L. 116–94, §105(a)(1)(B), designated existing provisions as subpar. (A) and inserted heading, substituted "Subject to subparagraph (B), in this section" for "In this section", and added subpar. (B).

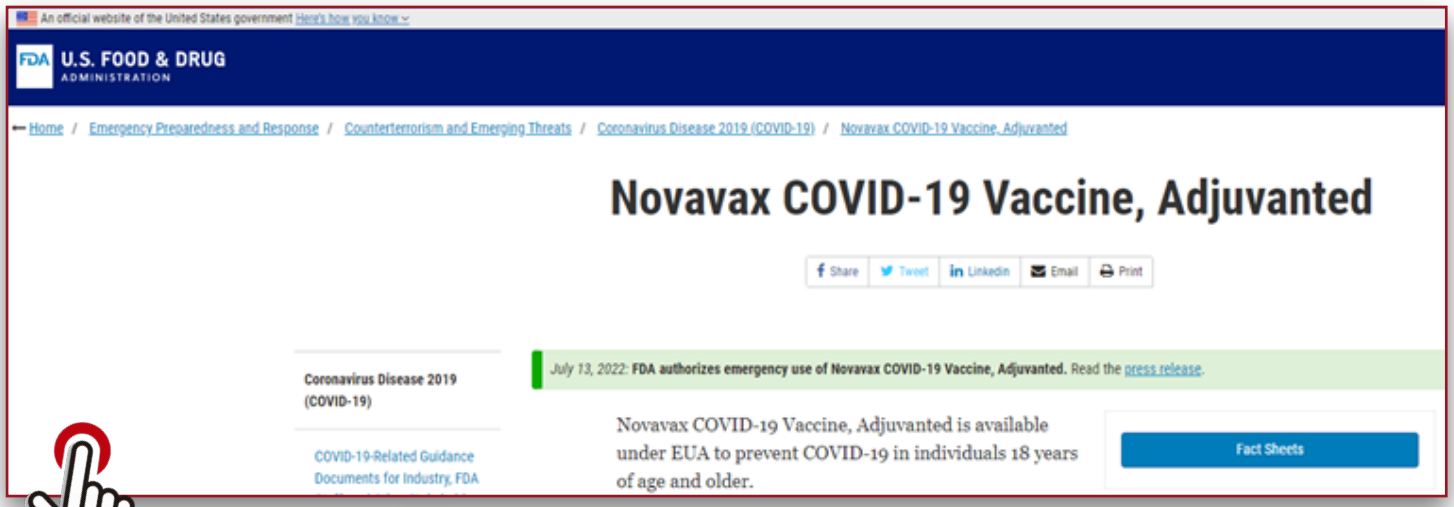
Subsec. (b)(3)(A). Pub. L. 116–94, §105(a)(2)(A), substituted "through 2023" for "through 2022".

Subsec. (b)(3)(B)(i). Pub. L. 116–94, §105(a)(2)(B)(i), substituted "through 2020" for "through 2019".Subsec. (b)(3)(B)(ii). Pub. L. 116–94, §105(a)(2)(B)(ii), substituted "2021 through 2023" for "2020 through 2022".

FDA APPROVES EUA FOR NOVAVAX ADJUVANTED COVID-19 VACCINE

On July 13, 2022, the FDA granted an Emergency Use Authorization (EUA) for Adjuvanted produced by Novavax. The two-dose series, administered three weeks apart is authorized for the prevention of COVID-19 in patients 18 and older.

https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/novavax-covid-19-vaccine-adjuvanted



The two-dose series, administered three weeks apart is authorized for the prevention of COVID-19 in patients 18 and older.

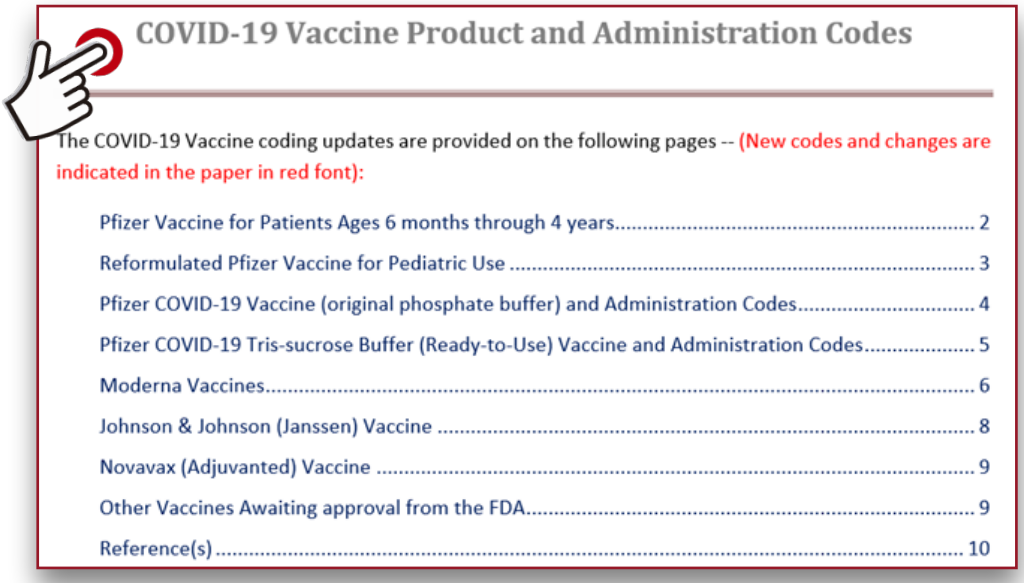
FDA APPROVES EUA FOR NOVAVAX ADJUVANTED COVID-19 VACCINE

Novavax Adjuvanted Product and Administration Codes

Code	CPT Long Descriptor	Mfr Vaccine Product / Procedure Name	Effective Date
91304	(Severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5 mL dosage, for intramuscular use) *(Report with administration codes 0031A)*	**Novavax** Covid-19 Vaccine NDC: 80631-1000-01	07/13/2022
0041A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5 mL; **first dose** *(Report with vaccine product 91304)*	**Novavax** Covid-19 Vaccine Administration – **1st Dose**	07/13/2022
0042A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5 mL; **second dose** *(Report with vaccine product 91304)*	**Novavax** Covid-19 Vaccine Administration – **Booster Dose**	07/13/2022

EUA Authorized for Ages 18 and older

For other COVID-19 vaccine and administration codes, please see **ParaRev's** updated COVID-19 Vaccine Product and Administration paper:



COVID-19 Vaccine Product and Administration Codes

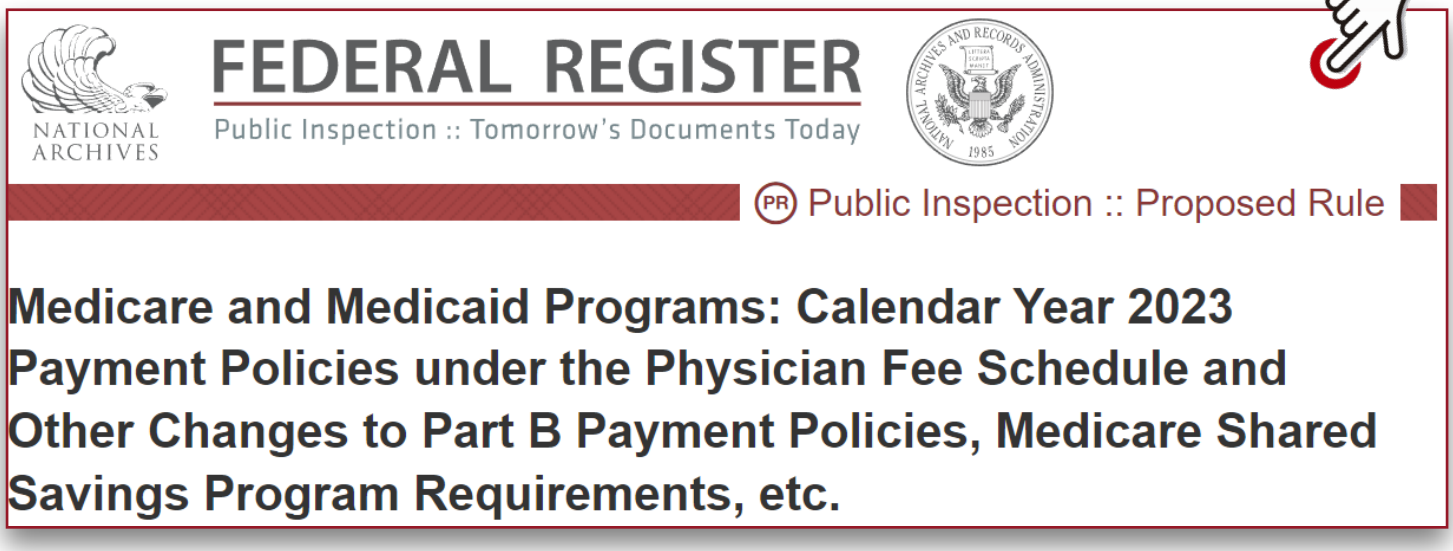
The COVID-19 Vaccine coding updates are provided on the following pages -- (New codes and changes are indicated in the paper in red font):

MPFS PROPOSED RULE ADDS ANOTHER MODIFIER FOR PAYABLE DRUGS

CMS HAS PROPOSED THAT HOSPITAL, PHYSICIAN, AND AMBULATORY SURGERY CENTER CLAIMS REPORTING EXPENSIVE DRUGS (OPPS STATUS K AND G) APPEND A NEW MODIFIER -- JZ -- TO THE DRUG HCPCS WHEN NO PORTION OF A SINGLE-USE VIAL IS CLAIMED AS WASTE.

The proposal is discussed beginning on page 491 of the unpublished version of the CY 2023 Payment Policies under the Physician Fee Schedule:

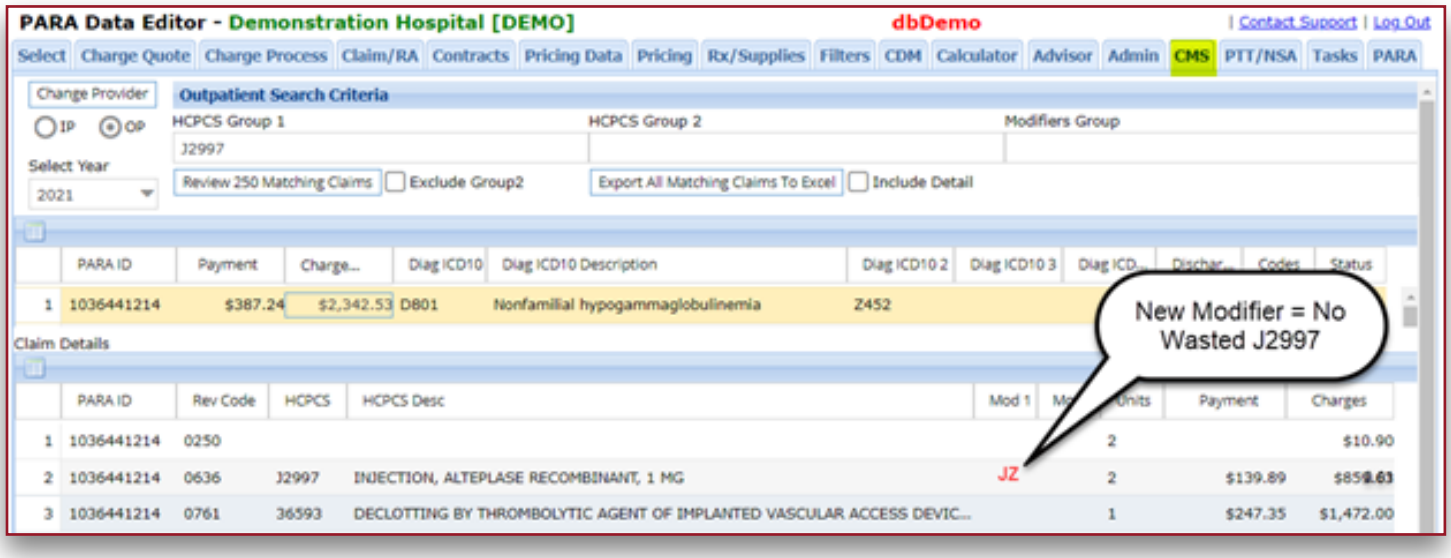
https://www.federalregister.gov/public-inspection/2022-14562/medicare-and-medicaid-programs-calendar-year-2023-payment-policies-under-the-physician-fee-schedule



Currently, hospitals are required to report the wasted portion of expensive drugs on a separate line with modifier JW appended to the HCPCS, but if no wasted portion of a single-use vial is claimed, neither a modifier nor a second line reporting the drug is required.New modifier JZ would be appended to the single-line HCPCS when no second line of wastage would be claimed, to verify that no portion was wasted.

For example, if the proposed rule is adopted, when the full contents of a 2-milligram vial of CathFlow®, J2997, is used for a declotting procedure, a claim to Medicare would append modifier JZ to J2997 as indicated in this screen shot from the **PARA Data Editor:** *(see next page)*

MPFS PROPOSED RULE ADDS ANOTHER MODIFIER FOR PAYABLE DRUGS



CMS hopes the modifier will improve billing data needed to facilitate refunds from drug manufacturers for wasted drugs. The Infrastructure Investment and Jobs Act (Pub. L. 117-9, November 15, 2021) requires drug manufacturers to issue a refund to CMS for certain discarded amounts from certain single-dose container or single-use package drug. To claim the maximum refund, CMS needs accurate data, and seeks to improve reporting from hospitals to ensure the refund amounts are appropriate.

Medicare's proposed rule indicates they are not confident the data from the JW modifier is adequate:

> "Under our current discarded drug policy, no modifier is required when there are no discarded amounts from a single use vial or single use package drug. However, we are aware that the JW modifier is often omitted on claims, and it is unclear whether the absence of the JW modifier on a claim for a single-dose container drug indicates that there were no discarded amounts or that the modifier was incorrectly omitted from the claim.
>
> This has led to incomplete data describing quantities of discarded amounts and the associated Medicare payments."...Because JW modifier data is incomplete and because refund amounts would rely on this data, we propose that for dates of service on or after January 1, 2023, the JW modifier be required on claims for all single-dose container or single use drugs for which any amount is discarded (as reflected in our current policy and proposed above), and a separate modifier be required on claims for these drugs when there are no discarded amounts. Specifically, we propose to require the use of a separate modifier, the JZ modifier, to attest that there were no discarded amounts."

MPFS PROPOSED RULE ADDS ANOTHER MODIFIER FOR PAYABLE DRUGS

Since 2017, Medicare has required hospitals to report the wasted portion of a single-use vial on a second line item for each payable drug HCPCS. The second line, with modifier JW appended to the drug HCPCS, allows CMS to monitor wastage while permitting the provider to receive reimbursement for the entire vial contents. If the new proposed rule is adopted, hospitals would report the JZ modifier if no wastage was claimed, for instance if an entire vial was administered to the patient. A new claim edit would reject any claim for an OPPS status K or G drug which failed to report either 1) the JZ modifier, or 2) a second line of the same HCPCS with modifier JW appended.

Here are a few more excerpts from the narrative of the proposed rule:

> "More than half of Medicare spending for discarded amounts in 2020 represents about 40 billing and payment codes (that is, HCPCS codes), for which 10 percent or more of the total charges for the drug were for discarded units. A large proportion of single source drugs with 10 percent or more discarded units are dosed based on patient's body weight or BSA. We note that the JW modifier data published on the CMS website is limited to only billing and payment codes that are published on the ASP Drug Pricing File. There are likely additional billing and payment codes payable under Medicare Part B available in single-dose containers that would be subject to the JW modifier policy and are not reflected in the data discussed above...."
>
> "...Because JW modifier data is incomplete and because refund amounts would rely on this data, we propose that for dates of service on or after January 1, 2023, the JW modifier be required on claims for all single-dose container or single use drugs for which any amount is discarded (as reflected in our current policy and proposed above), and a separate modifier be required on claims for these drugs when there are no discarded amounts. Specifically, we propose to require the use of a separate modifier, the JZ modifier, to attest that there were no discarded amounts. To align with the JW modifier policy, the JZ modifier would be required when there are no discarded amounts from single use vials or single use packages payable under Part B for which the JW modifier would be required if there were discarded amounts. So, on all claims for single use vials or single use packages payable under Part B, either the JW modifier would be used (on a separate line) to identify any discarded amounts or the JZ modifier (on the claim line with the administered amount) would be present to attest that there were no discarded amounts. We believe the proposed JZ modifier requirement would not increase burden on the provider because under the current JW modifier policy, the provider already needs to determine whether or not there are any discarded units from a single use vial or package, record discarded amounts in the patient medical record, and specify administered and discarded amounts on the claim form." CMS seeks comments on the proposed rule.

Comments may be submitted after the final publication of the proposed rule, expected on 7/29/2022. Interested parties may submit electronic comments on the proposed rule to http://www.regulations.gov. Follow the "Submit a comment" instructions.

RHC AND FQHC MENTAL HEALTH TELEHEALTH VISITS FOLLOWING PHE

On June 6, 2022, in MLN Article, *"Mental Health Visits via Telecommunications for Rural Health Clinics & Federally Qualified Health Centers,"* CMS revised in-person requirements for Mental Health Visits via Telecommunication for RHCs and FQHCs following the COVID-19 Public Health Emergency (PHE).

Per Section 304 of the Consolidated Appropriations Act (CAA) 2022, when a Medicare beneficiary receives mental health visits via telecommunications, RHCs and FQHCs will not require in-person visits until the 152nd day following the COVID-19 PHE.

The exception applies only to RHC and FQHC mental health services; all other providers must abide by the following Medicare requirements" No other changes were made to the mental health visit telehealth requirements.

The exception applies only to RHC and FQHC mental health services; all other providers must abide by the following Medicare in-person visit requirements for beneficiaries receiving mental health visits via telecommunications:

- At least 6 months prior to a telecommunication visit for mental health
- With limited exceptions, at least every 12 months during mental health telecommunications to diagnose, evaluate or treat the patient's mental health issues and conditions

RHC AND FQHC MENTAL HEALTH TELEHEALTH VISITS FOLLOWING PHE

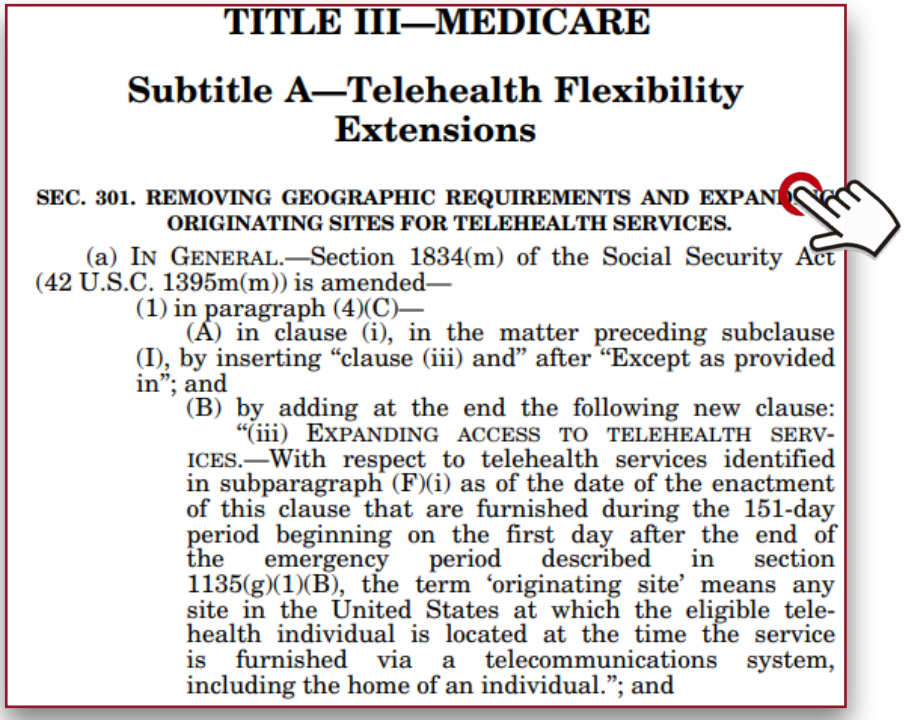
CMS provides a non-exclusive list of exceptions to the 12-month in-person visit when:

- The patient is in full or partial remission and needs only maintenance care
- The patient's condition may worsen, or an in-person visit may be disruptive
- The patient's care has been effective, but the patient may stop care with a required in-person visit
- The practitioner considers the patient clinically stable, but an in-person visit could impair the progress or create an undue hardship for the patient or the patient's family

Practitioners need to document circumstances leading to exceptions of the in-person visit.

Additional information is available through the following links:
Mental Health Visits via Telecommunications for Rural Health Clinics & Federally Qualified Health Centers

Section 304 of the Consolidated Appropriations Act (CAA) 2022



TITLE III—MEDICARE

Subtitle A—Telehealth Flexibility Extensions

SEC. 301. REMOVING GEOGRAPHIC REQUIREMENTS AND EXPANDING ORIGINATING SITES FOR TELEHEALTH SERVICES.

(a) IN GENERAL.—Section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)) is amended—

(1) in paragraph (4)(C)—

(A) in clause (i), in the matter preceding subclause (I), by inserting "clause (iii) and" after "Except as provided in"; and

(B) by adding at the end the following new clause:

"(iii) EXPANDING ACCESS TO TELEHEALTH SERVICES.—With respect to telehealth services identified in subparagraph (F)(i) as of the date of the enactment of this clause that are furnished during the 151-day period beginning on the first day after the end of the emergency period described in section 1135(g)(1)(B), the term 'originating site' means any site in the United States at which the eligible telehealth individual is located at the time the service is furnished via a telecommunications system, including the home of an individual."; and

PATIENT PREVAILS IN NSA DISPUTE WITH FACILITY

A miscommunication cost a facility $3,000 when a Good Faith Estimate (GFE) was issued to an uninsured patient with an incorrect CPT®. The cardiologist had scheduled a procedure but did not list the code for the intended procedure. The GFE was issued to the patient with a code that was priced $3,000 less than the intended procedure.

The patient initiated a Patient Provider Dispute Resolution (PPDR) and prevailed when the facility was unable to produce supportive evidence of not having reasonably expected the increased charges. The facility has allowed **ParaRev** to share the communication they received from CMS to allow other facilities and providers to prepare for potential PPDR events.

CMS used the email FederalPPDRinititation@cms.hhs.gov to send correspondences to facilities and providers to inform them that a patient has initiated a dispute and provide further instructions. **ParaRev** strongly encourages clients to add this email address to their address book to avoid having these notices go to spam folders.

From: CMS Federal PPDR Initiation <FederalPPDRInitiation@cms.hhs.gov>
Sent: Friday, May 20, 2022 2:04 PM
To: BusinessOffice <BusinessOffice@[redacted]
Subject: Reminder: We still need information to process your PPDR dispute

PPDR dispute status: Under review

PPDR reference number: DISP-[redacted]

The Selected Dispute Resolution Entity (SDRE), C2C Solutions, Inc., previously sent you a notice stating that CMS identified C2C Solutions, Inc. to review the case with **PPDR Reference Number DISP-**[redacted] We still need additional information from you to process this dispute.

Next steps:

Access https://nsa-idr.cms.gov/providerresponse/s/?guid=34c372c2-52bf-4c4c-a0a0-a060b8db63b7

https://nsa-idr.cms.gov/settlement/s/?guid=6daf2b31-55c0-41a1-82c2-cf4ed248f214 and send the following **within 5 business days of the date of this notice:**

- A copy of the Good Faith Estimate provided to the patient for this case
- A copy of the bill sent to the patient for the items or services under dispute
- Justification for why the billed amount was appropriate and based on unforeseen circumstances that couldn't have reasonably been anticipated when the Good Faith Estimate was provided

Include your PPDR reference number DISP-[redacted] **on all documents you send.**

Once we get this information, we'll send you a confirmation email from FederalPPDRInitiations@cms.hhs.gov and the SDRE will continue the PPDR process. If you don't respond within **5 business days of the date of this notice**, we will continue the PPDR process without this additional information, but you may not prevail in this dispute.

Resources

- Visit the No Surprises website for additional PPDR resources.

Contact information

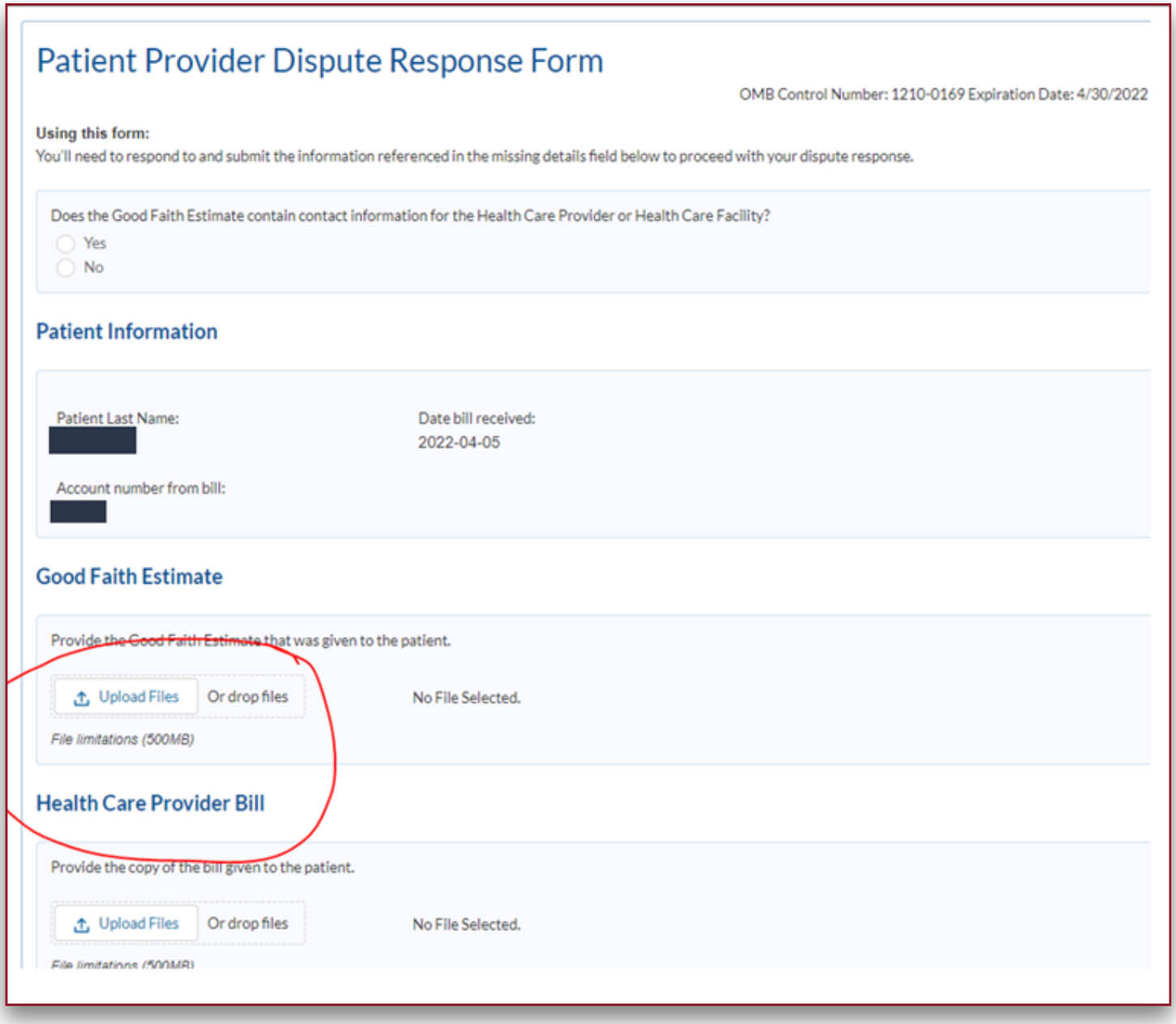
For questions, contact FederalPPDRQuestions@cms.hhs.gov and include your PPDR reference number above.

Thank you,

The Centers for Medicare & Medicaid Services

PATIENT PREVAILS IN NSA DISPUTE WITH FACILITY

The hyperlink in the email message took the facility to a CMS portal where they could complete an electronic form and upload the required documents.



Patient Provider Dispute Response Form

OMB Control Number: 1210-0169 Expiration Date: 4/30/2022

Using this form:
You'll need to respond to and submit the information referenced in the missing details field below to proceed with your dispute response.

Does the Good Faith Estimate contain contact information for the Health Care Provider or Health Care Facility?
- Yes
- No

Patient Information

Patient Last Name: [redacted]

Date bill received: 2022-04-05

Account number from bill: [redacted]

Good Faith Estimate

Provide the Good Faith Estimate that was given to the patient.

Upload Files | Or drop files | No File Selected.

File limitations (500MB)

Health Care Provider Bill

Provide the copy of the bill given to the patient.

Upload Files | Or drop files | No File Selected.

File limitations (500MB)

PATIENT PREVAILS IN NSA DISPUTE WITH FACILITY

According to the provider, the portal did not allow the facility to upload documents even though they were under the 500MB limit. They were able to contact CMS to get an address in which to send hard copies of documents. These are the updates shared internally at the facility.

5/25/22: Just keeping everyone in the loop on this. I received a voice mail from C2C Innovated Solutions they ae the contractor for the PPDR disputes for our area. The voicemail said to call them back and leave a detailed message and they would call me within one business day. I did try and upload the attachments again today and it still would not upload.

5/26/22: This morning I was able to talk to the No Surprises Help Desk who referred me to the CMS Help Desk. We were not able to resolve the issue of attaching the required documents to the Provider Dispute form so the option they gave me was to send a hard copy letter with the attachments. I did this. It is going out Fed Ex today! The letter and all attachments has been scanned into the encounter.

5/31/22: Another update! Checked FedEx tracking and package was received today and signed for by [redacted] and scanned into encounter. Also, [redacted] with C2C Innovative Solutions the contractor for the PPDR disputes called today. He said apparently there are other providers that are also having issues with uploading of documentation and getting their provider disputes submitted. He asked me for the FedEx address that I was given by the CMS Help Desk and he also wanted the particular steps I went through to try and get the documents uploaded and submitted electronically. He did say that it will take at least 30 days for them to review the dispute and I will be getting a letter once it has been reviewed detailing the decision.

PATIENT PREVAILS IN NSA DISPUTE WITH FACILITY

The next correspondence received by the facility was from the third party entity which adjudicated the case. That entity provided the facility with a detailed explanation of their findings and determination. That message is shared below.

PPDR dispute status: Determination made

PPDR reference number: DISP-[redacted]

[redacted] and [redacted] Medical Center,

The Selected Dispute Resolution Entity (SDRE) reviewed the information for DISP-[redacted] Based on our review, our decision is that [redacted] Medical Center has not provided credible evidence to demonstrate the difference between the amount billed and the Good Faith Estimate is medically justified and based on unforeseen circumstances that could not have been reasonably anticipated. The patient initially received a Good Faith Estimate (GFE) from [redacted] Medical Center on March 4, 2022, for a heart catheterization procedure. The GFE includes a total charge of $8,500.00 and a discounted rate of $5,100.00. On April 12, 2022, $100.00 was paid towards the balance of the billed charge.

[redacted] Medical Center submitted: a facsimile cover sheet, correspondence, a request to schedule surgery document, pre-catheterization instructions, a GFE, and billing statements dated April 5, 2022, and April 26, 2022.

When reviewing the provider records, the rebuttal indicates the physician did not specify the Current Procedural Terminology (CPT) code. Therefore, the GFE was based on an incorrect CPT code. The CPT code used on the GFE was 93453 - combined right and left cardiac catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, if performed. However, the documentation does not provide credible information that the difference between the billed charge and the expected charge for the item or service in the GFE reflected the costs of a medically necessary item or service and was based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the GFE was provided.

Therefore, the amount due is equal to the expected charge for the item or services on the GFE. The total amount due by the patient is $5,100.00. Since the patient already paid $100.00 towards this amount, the new adjusted amount due is $5,000.00. In addition, [redacted] Medical Center must refund the $25.00 administrative fee to the patient.

In conclusion, the decision of the SDRE is that the patient prevails.

Based on this decision, [redacted] must pay:

$5,100.00, which was the total, expected charges from the GFE minus the $25 administrative fee that the patient paid.

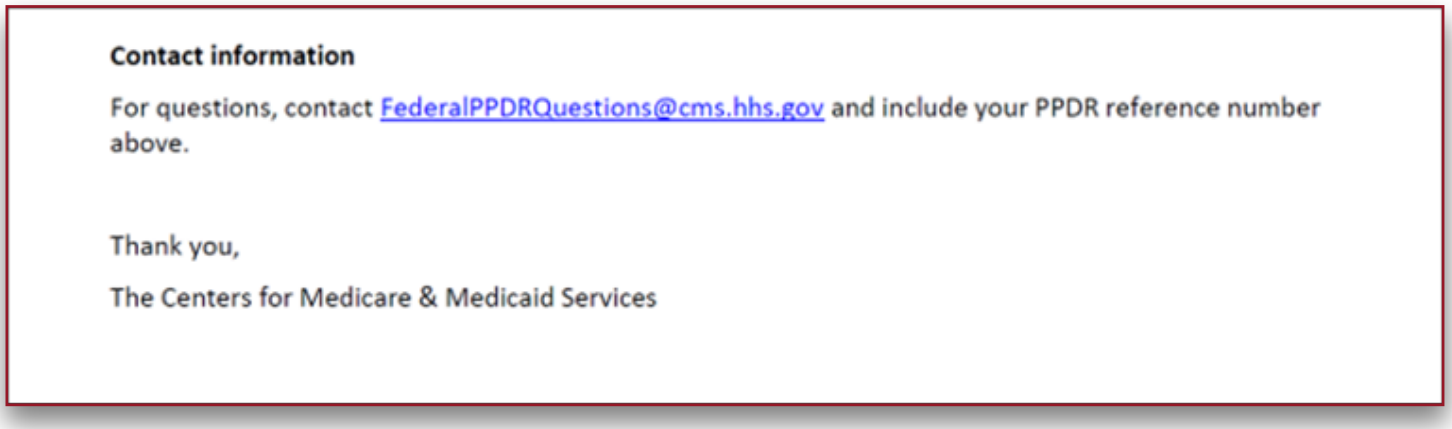
[redacted] must directly pay [redacted] Medical Center.

This decision is binding, unless there are claims of fraud or a misrepresentation of facts presented to support this case, in which case you may have the right to other legal remedies. For more information, see www.cms.gov/nosurprises/consumers.

Resources

- Visit the No Surprises website for additional PPDR resources.

PATIENT PREVAILS IN NSA DISPUTE WITH FACILITY



Contact information

For questions, contact FederalPPDRQuestions@cms.hhs.gov and include your PPDR reference number above.

Thank you,

The Centers for Medicare & Medicaid Services

This expensive error can be avoided in 2022 with good communication between convening facilities and ordering providers. In 2023 the convening facility/provider will have to include charges from co-providers which will include the primary service code and avoid costly errors. The following excerpt is provided from the regulations. It outlines what information must be provided from the co-facility/provider to the convening facility/provider.

eCFR :: 45 CFR 149.610 -- Requirements for provision of good faith estimates of expected charges for uninsured (or self-pay) individuals.

Content Requirements for Good Faith Estimate Information Submitted by Co-Providers or Co-Facilities to Convening Providers or Convening Facilities.

(1) Good faith estimate information submitted to convening providers or convening facilities by co-providers or co-facilities for inclusion in the good faith estimate (described inparagraph (c)(1)of this section) must include:

(i) Patient name and date of birth;

(ii) Itemized list of items or services expected to be provided by the co-provider or co-facility that are reasonably expected to be furnished in conjunction with the primary item or service as part of the period of care;

(iii) Applicable diagnosis codes, expected service codes, and expected charges associated with each listed item or service;

(iv) Name, National Provider Identifiers, and Tax Identification Numbers of the co-provider or co-facility, and the State(s) and office or facility location(s) where the items or services are expected to be furnished by the co-provider or co-facility; and(v) A disclaimer that the good faith estimate is not a contract and does not require the uninsured (or self-pay) individual to obtain the items or services from any of the co-providers or co-facilities identified in the good faith estimate.

SUPREME COURT INVALIDATES 2018-2019 340(B) PAYMENT CUTS

ON JUNE 15, 2022, THE SUPREME COURT OF THE UNITED STATES (SCOTUS) ISSUED A DECISION THAT MEDICARE IMPROPERLY REDUCED OPPS REIMBURSEMENT TO CERTAIN HOSPITALS WHICH PURCHASE DRUGS UNDER HRSA'S 340(B) PROGRAM IN 2018 AND 2019.

The full text of the court's decision is available at https://www.supremecourt.gov/opinions/21pdf/20-1114_09m1.pdf.)

The good news is that hospitals which endured reduced Medicare payments for drugs purchased under the 340(b) program may eventually recover the 340(b) cuts to reimbursement taken by Medicare in 2018 and 2019 – although how and when that might happen is not yet determined.

The bad news is that due to budget neutrality requirements, reversing the current payment policy could cause Medicare to fund the additional expense by cutting OPPS reimbursement in other areas. According to a study commissioned by the Federation of American Hospitals, even rural OPPS hospitals that were exempted from the 340(b) cuts could eventually be affected by the fallout:

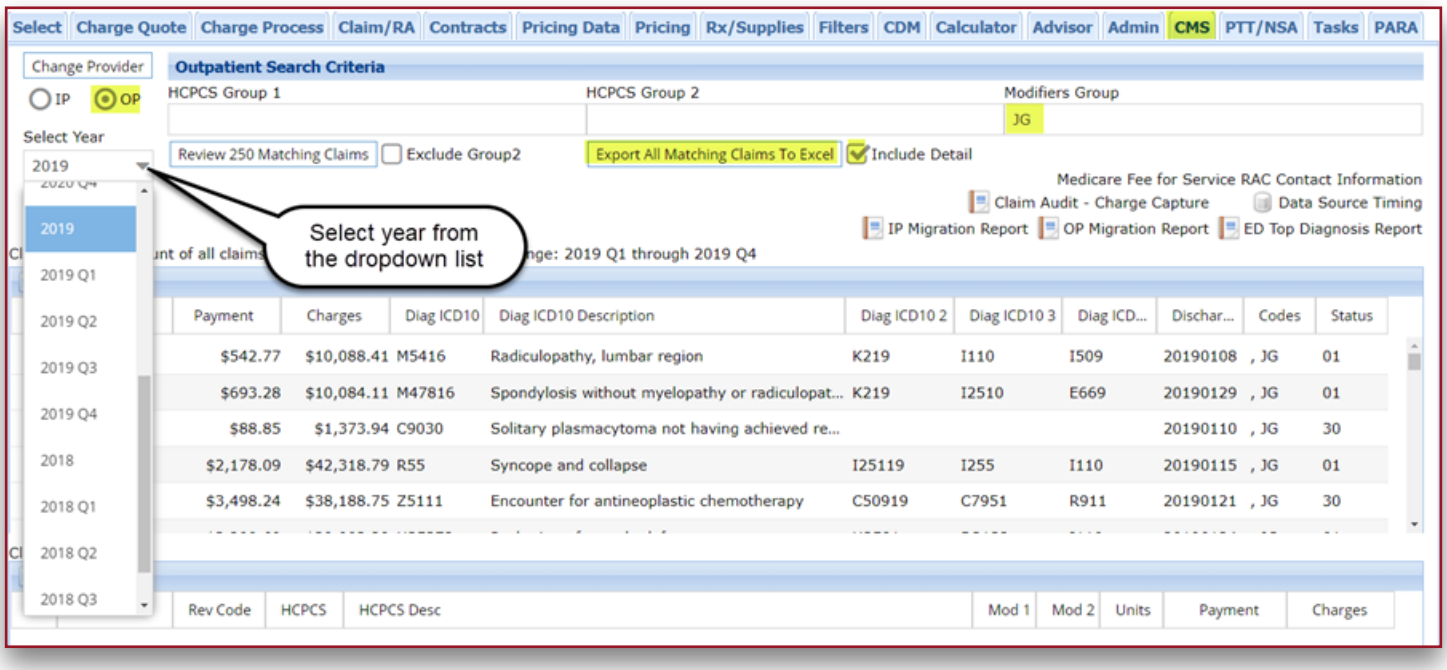
https://avalere.com/insights/opps-340b-policy-reversal-lowers-hospital-payment-and-increases-copays#

> … nearly half (49.4%) of all OPPS 340B hospitals would see a net payment decrease in total OPPS payments under a policy reversal. This occurs because the corresponding budget neutrality payment reduction for all non-drug items and services would outweigh the drug payment increase.
>
> The aggregate beneficiary cost-sharing amount for separately payable drugs across all OPPS 340B hospitals is estimated to increase by $472.8 million under a policy reversal. Of note, the specific cost-sharing amount a beneficiary pays for a drug or a service under OPPS is capped at the amount of inpatient hospital deductible, which is $1,484 in 2021.

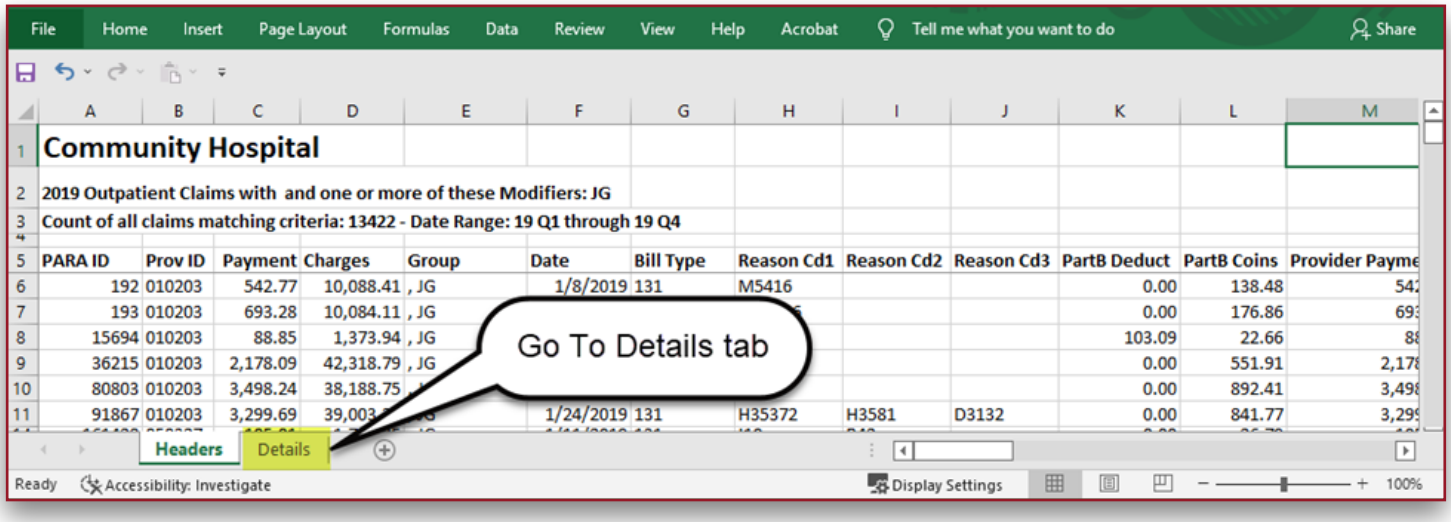
OPPS 340B Policy Reversal Lowers Hospital Payment and Increases Copays

SUPREME COURT INVALIDATES 2018-2019 340(B) PAYMENT CUTS

ParaRev clients may assess the impact of the 340(b) reductions by reviewing the outpatient claim lines adjudicated by original Medicare in prior years, namely 2018 and 2019, on the CMS tab of the **PARA Data Editor**. Simply enter "JG" in the modifier field, and download (with detail) a list of claims paid by CMS according to CMS published data for 2019 and 2020.The data is exactly as published by Medicare in the MEDPAR Limited Data Set.

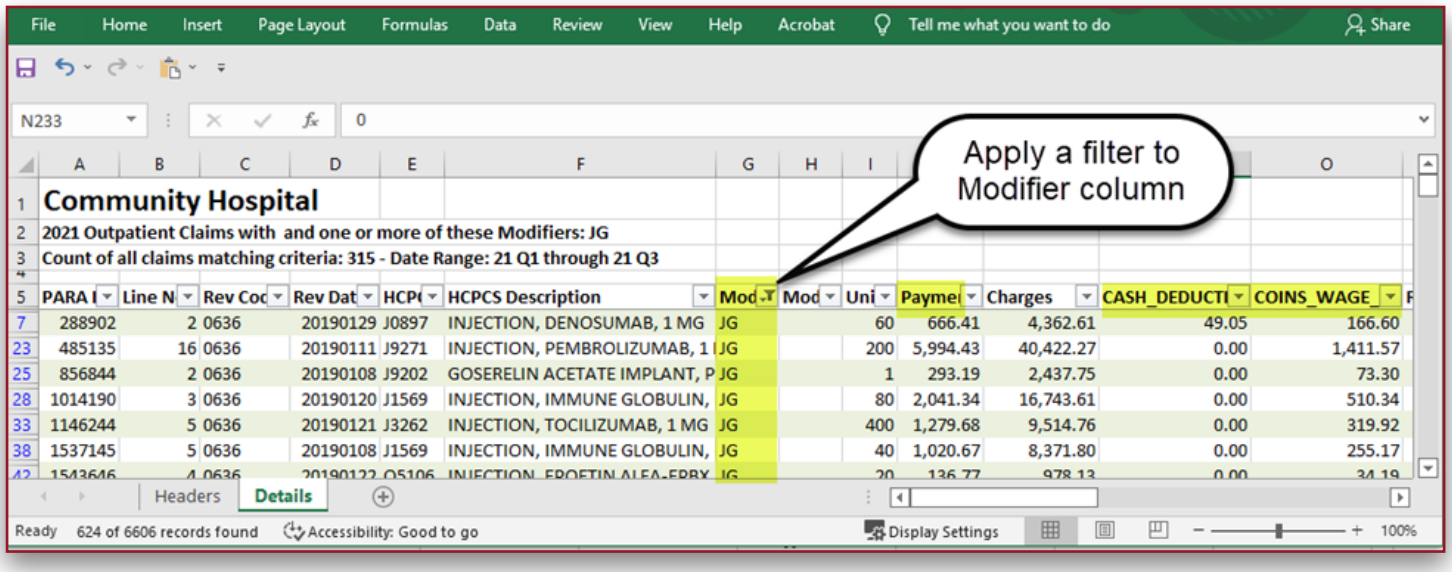


The downloaded spreadsheet offers two tabs - a list of claims (Headers), and line item details:



SUPREME COURT INVALIDATES 2018-2019 340(B) PAYMENT CUTS

On the **Details** tab, clients can filter the results to only those line items reported with modifier JG; the sum of the CMS Payment Amount, beneficiary deductible, and beneficiary coinsurance is the total "allowed" amount that was reduced under the 340(b) cuts:



PARA I	Line N	Rev Coc	Rev Dat	HCP(	HCPCS Description	Mod	Mod	Uni	Payme	Charges	CASH_DEDUCTI	COINS_WAGE_
288902	2	0636	20190129	J0897	INJECTION, DENOSUMAB, 1 MG	JG		60	666.41	4,362.61	49.05	166.60
485135	16	0636	20190111	J9271	INJECTION, PEMBROLIZUMAB, 1 I	JG		200	5,994.43	40,422.27	0.00	1,411.57
856844	2	0636	20190108	J9202	GOSERELIN ACETATE IMPLANT, P	JG		1	293.19	2,437.75	0.00	73.30
1014190	3	0636	20190120	J1569	INJECTION, IMMUNE GLOBULIN,	JG		80	2,041.34	16,743.61	0.00	510.34
1146244	5	0636	20190121	J3262	INJECTION, TOCILIZUMAB, 1 MG	JG		400	1,279.68	9,514.76	0.00	319.92
1537145	5	0636	20190108	J1569	INJECTION, IMMUNE GLOBULIN,	JG		40	1,020.67	8,371.80	0.00	255.17

> The American Hospital Association published a Special Bulletin on June 15, 2022 stating that "Now that the Supreme Court has ruled, we look forward to working with the Administration and the courts to develop a plan to reimburse 340B hospitals affected by these unlawful cuts while ensuring the remainder of the hospital field is not disadvantaged as they also continue to serve their communities."

https://www.aha.org/system/files/media/file/2022/06/2022-0615-Special-Bulletin-340B-Supreme-Court-Decision.pdf

SUPREME COURT INVALIDATES 2018-2019 340(B) PAYMENT CUTS

According to the AHA bulletin, the Supreme Court concluded that

> "[u]nder the text and structure of the statute," the case was "straightforward" as a matter of law: " Because HHS did not conduct a survey of hospitals' acquisition costs, HHS acted unlawfully by reducing the reimbursement rates for 340B hospitals."

(Although rates in 2020 could arguably be affected by the SCOTUS decision, reimbursement rates in 2021 and 2022 are not covered because CMS conducted a survey of hospital acquisition costs for those years.)

Beginning January 1, 2018, Medicare reduced OPPS reimbursement for separately payable (Status K) drugs purchased under the 340(b) program at certain hospitals. In 2018, CMS adjusted the reimbursement amount for 340(b) drugs at the average sales price (ASP) minus 28.5 percent, although certain hospitals were excepted from the payment adjustment policy.In 2019, CMS dropped the reduction to ASP minus 22.5%.

Drugs that were not acquired through the 340(b) program were paid under the OPPS at ASP+6 percent in both 2018 and 2019. Affected hospitals are required to append modifier "JG" (Drug or biological acquired with 340B drug pricing program discount) to outpatient claims reporting payable drugs to facilitate the discounted rate of payment.

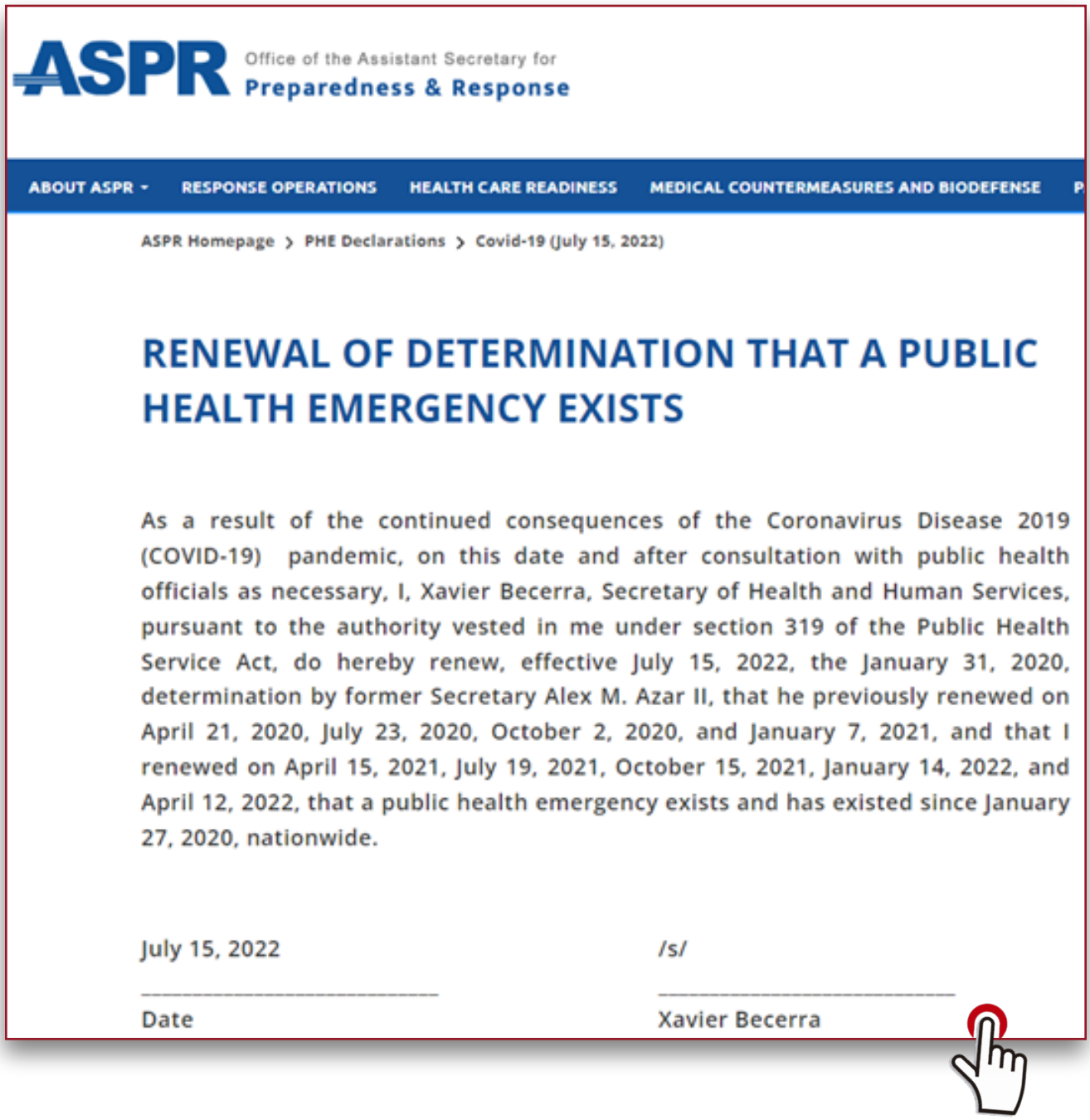
In 2019, CMS calculated payments made on drug charges with the JG modifier appended at .775 of the ASP (in other words, ASP minus 22.5%.) That rate is lower than standard OPPS methodology of 106% ASP (ASP plus 6%.) Therefore, for every $100 in allowable paid on lines reporting modifier JG in 2019, affected hospitals might recover an additional $36.77.

However, since 20% of the allowable would have been adjudicated to beneficiary liability, there will be some negotiation over the precise amount that CMS will pay – and where the money will come from, since budget neutrality requires the additional payments to be offset from other OPPS expenditures.

HHS EXTENDS PHE THROUGH OCTOBER 13, 2022

On July 15, 2022, Xavier Becerra, the Secretary of Health and Human Services, renewed the national Public Health Emergency (PHE) again for up to an additional 90-day period. This latest extension will expire on **October13, 2022,** unless the HHS Secretary determines the PHE is over or extends the PHE.

https://aspr.hhs.gov/legal/PHE/Pages/covid19-15jul2022.aspx



ASPR Office of the Assistant Secretary for Preparedness & Response

ABOUT ASPR | RESPONSE OPERATIONS | HEALTH CARE READINESS | MEDICAL COUNTERMEASURES AND BIODEFENSE | P

ASPR Homepage > PHE Declarations > Covid-19 (July 15, 2022)

RENEWAL OF DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS

As a result of the continued consequences of the Coronavirus Disease 2019 (COVID-19) pandemic, on this date and after consultation with public health officials as necessary, I, Xavier Becerra, Secretary of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, do hereby renew, effective July 15, 2022, the January 31, 2020, determination by former Secretary Alex M. Azar II, that he previously renewed on April 21, 2020, July 23, 2020, October 2, 2020, and January 7, 2021, and that I renewed on April 15, 2021, July 19, 2021, October 15, 2021, January 14, 2022, and April 12, 2022, that a public health emergency exists and has existed since January 27, 2020, nationwide.

July 15, 2022 /s/

Date Xavier Becerra

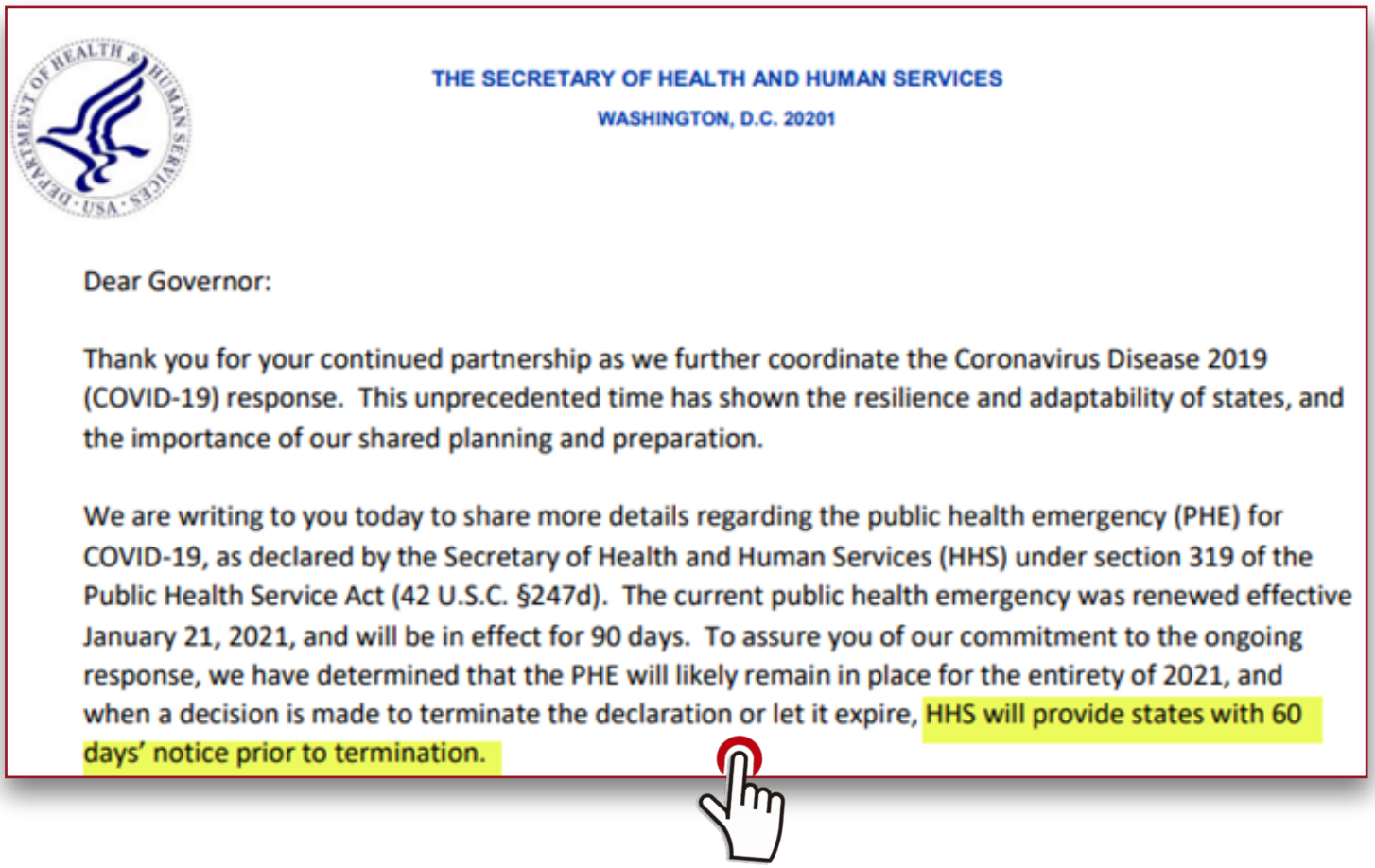
HHS EXTENDS PHE THROUGH OCTOBER 13, 2022

The **PHE Declaration Questions and Answers** webpage states that the PHE may be terminated either at the end of the 90-day extension or until the HHS Secretary declares the PHE no longer exists:

https://www.phe.gov/Preparedness/legal/Pages/phe-qa.aspx#faq7

In a letter dated 01/01/2021, HHS informed state governors that the HHS will provide a 60-day notice before ending the PHE. We provide an excerpt on the following page.

https://ccf.georgetown.edu/wp-content/uploads/2021/01/Public-Health-Emergency-Message-to-Governors.pdf



THE SECRETARY OF HEALTH AND HUMAN SERVICES

WASHINGTON, D.C. 20201

Dear Governor:

Thank you for your continued partnership as we further coordinate the Coronavirus Disease 2019 (COVID-19) response. This unprecedented time has shown the resilience and adaptability of states, and the importance of our shared planning and preparation.

We are writing to you today to share more details regarding the public health emergency (PHE) for COVID-19, as declared by the Secretary of Health and Human Services (HHS) under section 319 of the Public Health Service Act (42 U.S.C. §247d). The current public health emergency was renewed effective January 21, 2021, and will be in effect for 90 days. To assure you of our commitment to the ongoing response, we have determined that the PHE will likely remain in place for the entirety of 2021, and when a decision is made to terminate the declaration or let it expire, HHS will provide states with 60 days' notice prior to termination.

STAT REVENUE

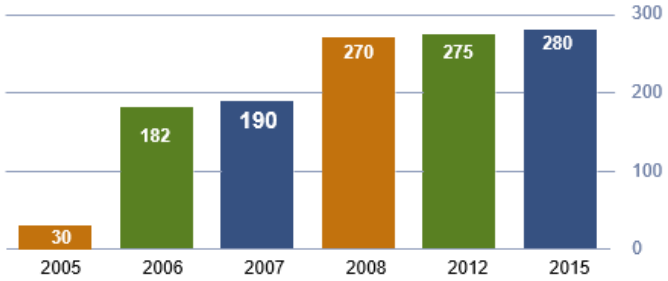
Is Your Hospital Losing MILLIONS to Inaccurate Medicare Transfer DRG Reductions?

*Transfers to **post-acute care** have **increased by 74%** since 2005. Government payers **automatically reduce payments** on all post-acute transfers regardless of outcome.*

*Tracking specific post-acute discharges for underpayment risk is complicated. **No software or clearinghouse data can effectively solve this problem for you.***

Hospitals are **exposed to transfer related underpayments** when discharged patients do not, or cannot, follow post-acute care instructions. Complex reimbursement rules, a national rise in post-acute discharges, and unforeseen patient circumstances can be **costing your hospital millions of dollars in lost revenue!**

CMS Transfer DRGs Skyrocket Since 2005



STAT Revenue's Transfer-DRG Review is BETTER

***STAT Revenue* overcomes Medicare and Medicare Advantage's major obstacles to recover substantial revenue.**

Why Our Post-Acute Transfer Review is Better:

- Big firm experience, small firm personalization. Our analysts leverage technology, decades of experience, and industry leading methodology to uncover more revenue.
- Our retrospective review can uncover lost Medicare revenue from the past 4 years.
- *STAT* Revenue reviews ALL Medicare & Medicare Advantage post-acute transfer discharges.
- Every identified claim is independently *researched* and *verified* by our team.
- *STAT* Revenue's strategic approach does NOT depend on outdated clearinghouse data, and leads to greater recovery efforts, even behind other teams and vendors.
- *STAT* Revenue ensures claim adjustment and tracking through adjudication are always in compliance.

Over $3 million in post-acute transfer related underpayments RECOVERED by ***STAT* Revenue.**

-University Hospital on Epic

***STAT* Revenue** IDENTIFIED over **$3.5 million** in transfer related underpayments.

-Hospital system in Ohio

MLN CONNECTS

PARA invites you to check out the mlnconnects page available from the Centers For Medicare and Medicaid (CMS). It's chock full of news and information, training opportunities, events and more! Each week PARA will bring you the latest news and links to available resources. Click each link for the PDF!

Thursday, July 21, 2022

News

- 988 Suicide & Crisis Lifeline Availablel Nationwide
- COVID-19: Novavax Vaccine, Adjuvanted — New Codes
- Allergy & Immunology: Comparative Billing Report in July
- Inpatient Rehabilitation Facilities: Care Compare July Refresh
- Long-Term Care Hospitals: Care Compare July Refresh
- Hospices & Home Health Agencies: Submit Technical Expert Panel Nominations by August 12
- Skilled Nursing Facility Provider Preview Reports: Review by August 15
- Opioid Treatment Programs: Comment by September 6

Compliance

- Implanted Spinal Neurostimulators: Document Medical Records

Information for Patients

- Medicare Savings Programs Help Pay Premiums

TRANSMITTALS

3

There were THREE new or revised Transmittals released this week.

To go to the full Transmittal document simply click on the screen shot or the link.

TRANSMITTAL R11504CP

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11504	**Date: July 21, 2022**
	Change Request 12792

SUBJECT: Modification of Existing Common Working File (CWF) Editing for Preventive Services

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to modify existing Common Working File (CWF) editing for preventive services. In some instances, when claims are paid outside the CWF, the beneficiary's claim history is not updated in the CWF, leading to incorrect claim's history. To avoid this and make CWF information more accurate, this CR allows frequency limitation editing to be overridden by contractors. In addition, this CR updates IOM Pub.100-04, Chapter 4, Section 300.5.

EFFECTIVE DATE: January 1, 2023
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 3, 2023

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	4/300/300.5/ General Claims Processing Information

III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

TRANSMITTAL R11505DEMO

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-19 Demonstrations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11505	**Date: July 21, 2022**
	Change Request 12791

SUBJECT: Concatenation of Multiple Separate Comma-Separated Values Files to One File - Update to CR 12492 - Implementation

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update the number of files received by Companion Data Services (CDS) and Peraton on a monthly basis for the monthly report created by Fiscal Intermediary Shared System (FISS) as requested by Centers for Medicare & Medicaid Services (CMS) in CR 12492. The monthly report provides details on the total number of claims and dollars that were processed under the Facility Performance Payment Adjustment (PPA) for the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) model.

EFFECTIVE DATE: January 1, 2023
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 3, 2023

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N/A	N/A

III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Demonstrations

TRANSMITTAL R11503OTN

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-20 One-Time Notification	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11503	**Date: July 21, 2022**
	Change Request 12790

SUBJECT: Corrections to Processing of Canceled Home Health Notices of Admission and of Period Sequence Edits

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to modify Original Medicare systems to ensure prior periods are updated correctly when a Notice of Admission is canceled. It also ensures medical review information is not removed when claims are subsequently adjusted due to period sequence edits.

EFFECTIVE DATE: January 1, 2023 - Claims processed on or after this date.
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 3, 2023

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N/A	

III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:
One Time Notification

MEDLEARNS

0

There were NO new or revised MedLearn released this week.

To go to the full Transmittal document simply click on the screen shot or the link.

FOR YOUR INFORMATION

*The preceding materials are for instructional purposes only. The information is presented "as-is" and to the best of **ParaRev's** knowledge is accurate at the time of distribution. However, due to the ever changing legal/regulatory landscape this information is subject to modification, as statutes/laws/regulations or other updates become available.*

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PARAREV CorroHealth

FOR YOUR INFORMATION

ParaRev is excited to announce we have joined industry leader **CorroHealth** to enhance the reach of our offerings! **ParaRev** services lines are additive in nature strengthening **CorroHealth's** impact to clients' revenue cycle. In addition, you now have access to a robust set of mid-cycle tools and solutions from **CorroHealth** that complement **ParaRev** offerings.

In terms of the impact you'll see, there will be no change to the management or services we provide. The shared passion, philosophy and cultures of our organizations makes this exciting news for our team and you, our clients.

While you can review the **CorroHealth** site HERE, we can coordinate a deeper dive into any of these solutions. Simply let us know and we'll set up a meeting to connect.

As always, we are available to answer any questions you may have regarding this news. We thank you for your continued partnership.