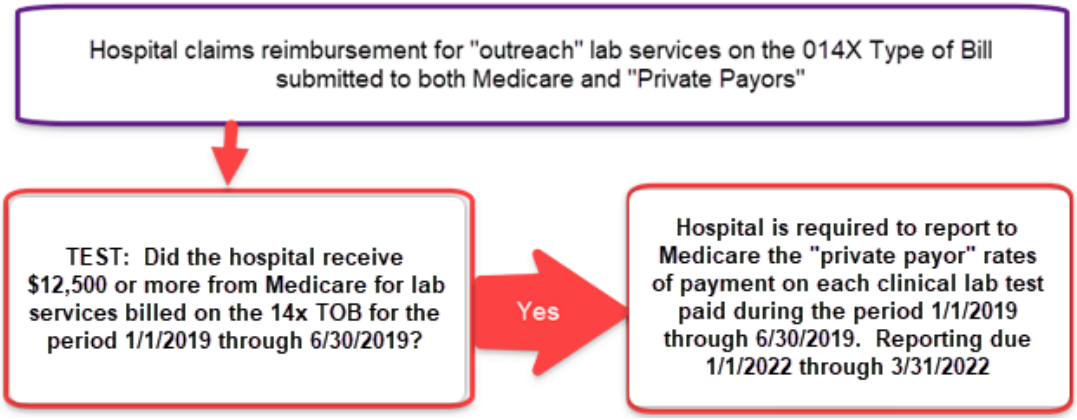
PAMA Private Payor Lab Payment Rate Reporting

In the 2019 OPPS Final Rule, Medicare added a new reporting requirement to hospital "outreach" laboratories which submit claims for non-patient services, i.e. blood sample processing without patient contact, on the "non-patient services" 14X type of bill (TOB.)

If a hospital received greater than $12,500 in Medicare revenues/reimbursement for non-patient service claims (billed on the 141 TOB) for dates of service between January 1, 2019 and June 30, 2019, then that hospital must report the private payor rates paid on lab tests during the same 6-month period, January 1 through June 30 2019, during the reporting period January 1, 2022 through March 31, 2022. (CMS has extended the reporting period deadline twice, but we don't expect another extension.)



CMS will collect private-payor data from hospitals for January through June of 2019, and use it to develop the overall weighted median payment rate for each test under the Clinical Laboratory Fee Schedule (CLFS). The weighted median will then serve as the basis of reimbursement for three years beginning in 2021.

Medicare clarified reporting requirements in an MLN article published in late February, 2019:

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE19006.pdf

Medicare Part B Clinical Laboratory Fee Schedule: Revised Information for Laboratories on Collecting and Reporting Data for the Private Payor Rate-Based Payment System

Hospitals conducting "outreach" laboratory service should verify whether the 141 type of bill was used to report "non-patient services" for lab testing. Regardless if the outreach lab services are reported under the same NPI as the hospital, the hospital must evaluate whether it meets two other tests, and report private payor data if it meets the tests for an "applicable laboratory."

Hospitals with labs billing on the 141 TOB are required to report payment data if:

- the hospital receives more than $12,500 in Medicare revenue/reimbursement for non-patient clinical lab services reported on bill type 141 in the period January 1 through June 30 2019, and
- the majority of revenue/reimbursements received from Medicare for services billed on the 141 bill type were paid under the Clinical Lab Fee Schedule (this is highly likely for TOB 141 claims.)

If a hospital is required to report, private payor payment data must be collected for the period 1/1/19 through 6/30/19, analyzed, validated, and reported to Medicare in the next reporting window. The window for reporting this data to Medicare has been delayed twice; reports will be accepted after January 1, 2022, but no later than March 31, 2022. Significant penalties (of up to $10,017 per violation per day) may apply if reporting is not complete, accurate, and timely. There is no exception for Critical Access Hospitals.

To determine if a hospital is required to report payment data, the central question is whether the hospital received $12,500 in reimbursement from Medicare (not including managed Medicare) during the data collection period January through June 2019 for non-patient lab testing.

ParaRev clients can reasonably assess whether the $12,500 threshold was met by contacting their ParaRev Account Executive. ParaRev purchases Medicare outpatient claims data for prior periods, and this data includes payments made on the 14X type of bill by Medicare. We have 2018 and Q1 2019, Q2 will be available soon.

If the sum of payments on 141 TOB indicate that the hospital has met or exceeded the $12,500 threshold in the period January through June, 2019, then the hospital should prepare to report data for the January-June 2019 data collection period.

ParaRev offers assistance with generating the data required for reporting private payor rates. The ParaRev Data Editor offers the ability to analyze electronic remittance files to quickly generate a spreadsheet of the allowable rate paid by CPT® codes on 141 bill types. This data will be configured into the required format for Medicare reporting. Clients will likely have some payments that will require manual research if not paid on a submitted 835 file, since ParaRev cannot research payments submitted on paper remittances.

To learn more about ParaRev's Lab Payment Reporting Analytical Services, please contact your ParaRev account executive (Sandra LaPlace at slaplace@pararevenue.com, or Violet Archuleta-Chiu at varchuleta@pararevenue.com.)

Data Collection and Reporting Schedule:

January 1, 2019 through June 30, 2019 – Collect Payment Data on 014X "outreach" lab claims

January 1, 2022 through March 31, 2022 – Report Payment Data to Medicare

A link and an excerpt from the Medicare MLN Matters publication on this topic is provided below:

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE19006.pdf

APPLICABLE INFORMATION

The applicable laboratory along with its reporting entity (we provide more information about reporting entities below) are responsible for collecting applicable information and reporting that data to CMS.

Applicable information includes three major components:

1. The specific HCPCS code associated with the test;
2. The private payor rate for each test for which final payment has been made during the data collection period;
3. The associated volume for each test.

Private Payor Defined

The definition of the term "private payor" is:

1. A health insurance issuer as defined in Section 2791(b)(2) of the Public Health Service (PHS) Act); Or
2. A group health plan as defined in Section 2791(a)(1) of the PHS Act); Or
3. A Medicare Advantage plan under Part C as defined in Section 1859(b)(1) of the Social Security Act (the Act); Or
4. A Medicaid Managed Care Organization (MCO) (as defined in Section 1903(m) of the Act).

All "private payor" payments received for a 14X TOB, even payments received for a service date prior to January 1, 2019, must be reported if the payment was received between 1/1/19 and 6/30/19. Therefore, providers will need to identify the universe of commercial 14X TOB claims that were outstanding as of 1/1/19 as well as created during the reporting period in order to match payments received from 1/1/19 through 6/30/19 to the 14X bill type alone. Hospitals should not report payments received on other bill types (such as 131); only non-patient service payments are to be reported.

Medicare updated an FAQ document on September 9, 2019 at the following link:

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2019-CLFS-FAQs.pdf

Frequently Asked Questions
CY 2019 Medicare Physician Fee Schedule Final Rule
Revisions to the Medicare Clinical Diagnostic Laboratory Tests Payment System

Excerpts from the 2019 Clinical Lab Fee Schedule Final Rule regarding penalties and certification are provided on the following pages.

https://www.govinfo.gov/content/pkg/FR-2016-06-23/pdf/2016-14531.pdf

Federal Register / Vol. 81, No. 121 / Thursday, June 23, 2016 / Rules and Regulations; page 41038

"…We proposed to apply a civil monetary penalty (CMP) to an applicable laboratory that fails to report or that makes a misrepresentation or omission in reporting applicable information. We proposed to require all data to be certified by the President, Chief Executive Officer (CEO), or Chief Financial Officer (CFO) of an applicable laboratory before it is submitted to CMS. As required by section 1834A(a)(10) of the Act, certain information disclosed by a laboratory under section 1834A(a) of the Act is confidential and may not be disclosed by the Secretary or a Medicare contractor in a form that reveals the identity of a specific payor or laboratory, or prices, charges or payments made to any such laboratory, with several exceptions. We are revising the certification and CMP policies in the final rule to require that the accuracy of the data be certified by the President, CEO, or CFO of the reporting entity, or an individual who has been delegated to sign for, and who reports directly to such an officer. Similarly, the reporting entity will be subject to CMPs for the failure to report or the misrepresentation or omission in reporting applicable information. Additionally, we are updating the CMP amount to reflect changes required by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act of 2015, Pub. L. 114–74, November 2, 2015).

…

Comment: Several commenters commented on the proposed CMPs of up to $10,000 per day per violation and said the amount should be reconsidered, particularly for community laboratories that cannot afford such penalties. The commenters also suggested that CMS only apply penalties in cases where there is evidence that a laboratory intentionally provided inaccurate or mistaken information.

Response: The statute authorizes CMPs of up to $10,000 per day per violation. However, in situations where our review reveals that the data submitted is incomplete or incorrect, we will work with the OIG to assess whether a CMP should be applied, and if so, the appropriate amount based on the specific circumstances. Although the statute authorizes CMPs of up to $10,000 per day per violation, we recognize that this is the maximum statutory amount, and not a minimum. The actual penalty imposed will be determined based on the facts and circumstances of each violation.

We note that this amount was recently amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act of 2015, Public Law 114–74, November 2, 2015) (the 2015 Act), which amends the Federal Civil Penalties Inflation Adjustment Act of 1990 (the Inflation Adjustment Act) (Pub. L. 101–410, 104 Stat. 890 (1990) (codified as amended at 28 U.S.C. 2461 note 2(a)). The Inflation Adjustment Act required all agencies, including HHS, to adjust any CMPs within their jurisdiction by increasing the maximum CMP or the range of minimum and maximum CMPs, as applicable, for each CMP by the cost-of-living adjustment.

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The 2015 Act was enacted to improve the effectiveness of civil monetary penalties and to maintain their deterrent effect. Among other things, it revises the method of calculating inflation adjustments so that, instead of the significant rounding methodology applied under the Inflation Adjustment Act, penalty amounts are now simply rounded to the nearest $1. Accordingly, in applying the requirements of the Inflation Adjustment Act, as amended, to the penalty amounts specified in section 1834A(a)(9) of the Act, the Secretary may assess CMPs of up to $10,017 per day per violation beginning on the effective date of this rule. We have revised § 414.504(e) to reflect this statutory adjustment. The 2015 Act also requires agencies to publish annual adjustments not later than January 15 of every year after publication of the initial adjustment. Therefore, subsequent to this initial adjustment, CMP adjustments applicable to section 1834A of the Act will be updated annually through regulations published by the Secretary no later than January 15 of every year.

Comment*:* Several commenters commented on the proposed CMPs of up to $10,000 per day per violation and said the amount should be reconsidered, particularly for community laboratories that

cannot afford such penalties. The commenters also suggested that CMS only apply penalties in cases where there is evidence that a laboratory intentionally provided inaccurate or mistaken information.

Response*:* The statute authorizes CMPs of up to $10,000 per day per violation. However, in situations where our review reveals that the data submitted is incomplete or incorrect, we will work with the OIG to assess whether a CMP should be applied, and if so, the appropriate amount

based on the specific circumstances. Although the statute authorizes CMPs of up to $10,000 per day per violation, we recognize that this is the maximum statutory amount, and not a minimum. The actual penalty imposed will be determined based on the facts and circumstances of each violation.

We note that this amount was recently amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act of 2015, Public Law 114–74, November 2, 2015) (the 2015 Act), which amends the Federal Civil Penalties Inflation Adjustment Act of 1990 (the Inflation Adjustment Act) (Pub. L. 101–410, 104 Stat. 890 (1990) (codified as amended at 28 U.S.C. 2461 note 2(a)). The Inflation Adjustment Act required all agencies, including HHS, to adjust any CMPs within their jurisdiction by increasing the maximum CMP or the range of minimum and maximum CMPs, as applicable, for each CMP by the cost-of-living adjustment. The 2015 Act was enacted to improve the effectiveness of civil monetary penalties and to maintain their

deterrent effect. Among other things, it revises the method of calculating inflation adjustments so that, instead of the significant rounding methodology applied under the Inflation Adjustment Act, penalty amounts are now simply rounded to the nearest $1. Accordingly, in applying the requirements of the Inflation Adjustment Act, as amended, to the penalty amounts specified in section 1834A(a)(9) of the Act, the Secretary may assess CMPs of up to $10,017 per day per violation

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this initial adjustment, CMP adjustments applicable to section 1834A of the Act will be updated annually through regulations published by the Secretary no later than January 15 of every year.

Comment: Several commenters requested clarification as to what constitutes an error that warrants a penalty, and stated that CMS should not apply any penalties or sanctions for reporting errors until an appeals process is outlined. Some commenters stated that CMS indicated in the proposed rule that full implementation of the new CLFS regulations will take between 5 and 6 years, and suggested that no penalties be assessed during this time.

Response: As previously mentioned, following the publication of this final rule, we will issue additional guidance on the assessment of CMPs, including what would constitute a failure to report or a misrepresentation or omission in reporting. We also note that we do not intend to assess CMPs for minor errors.

The actual penalty imposed will be determined based on the facts and circumstances of each violation. While full implementation of the new CLFS regulations will take several years, it is critical that reporting entities provide accurate and complete information at the outset so that accurate prices can be set, and while we do not expect that CMPs will be assessed frequently, we believe the ability to assess CMPs on reporting entities when appropriate is consistent with our statutory

authority. Section 1834A(a)(9)(B) of the Act further provides that the provisions of section 1128A of the Act (other than sections (a) and (b)) shall apply to a CMP under this paragraph in the same manner as they apply to a CMP or proceeding under section 1128A(a) of the Act.

Comment: A commenter stated that the economics and other characteristics of the laboratory industry differ greatly from the pharmaceutical industry making the comparison to Part B drugs inapplicable.

Response: We agree there are important differences between the pharmaceutical industry and the laboratory industry, but believe the general approach taken for the application of CMPs for violations in reporting drug prices is an appropriate model to consider when we develop guidance on the application of CMPs for violations in reporting of applicable information.

Comment: A commenter stated that CMPs can be an effective tool for encouraging data reporting and ensuring compliance with the PAMA reporting obligations but that there will be significant confusion within the laboratory community initially. The commenter requested that CMS not impose CMPs during the initial cycle on any laboratory that has shown a good faith effort to comply with the

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reporting requirements, and that CMS should notify applicable laboratories of their reporting obligations to ensure compliant reporting and to reduce the likelihood of penalties.

***Response**:* We appreciate the commenter's understanding of the important role of CMPs in ensuring accurate and complete data reporting and acknowledge the commenter's concerns regarding the provision of data during the initial reporting period. We are uncertain as to what the

commenter means by ''any laboratory that has shown a good faith effort to comply with the reporting requirements'' As we have noted previously, we do not intend to assess CMPs for minor errors, and will provide additional information in subregulatory guidance to facilitate compliant reporting and to reduce the likelihood of penalties. Additionally, we are clarifying in § 414.504(e) that the CMPs will be assessed at the reporting entity level, not at the applicable laboratory level, to ensure consistency with the data reporting and certification requirements that the reporting entity is obligated to follow, as addressed in the other paragraphs in § 414.504.

***Comment**:* Some commenters stated that smaller laboratories without sufficient administrative staff face challenges in reporting as compared to larger, well-resourced laboratories. These commenters suggested that the size of the penalty should correspond to the size of the laboratory, so that laboratories with limited resources would not be forced to close as a result of such penalties.

***Response**:* We will consider all relevant information when determining the amount of a CMP, and we will work with the OIG to ensure that any penalties assessed are fairly applied. The purpose of PAMA is to collect complete and accurate data in order to set payment rates, not to force a laboratory to close as a result of a CMP assessment.

***Comment**:* Some commenters were concerned that the period to understand and comply with the data requirements is too short and could compromise the integrity of the data submitted.

***Response**:* In section II.D of this final rule, we discuss our final data collection and reporting process, which is changed from our proposal in the proposed rule. Under the process we are adopting in this final rule, applicable laboratories will have a 6-month data collection period, followed by a 6-month period between the end of the data collection period and the beginning of the data reporting period to allow applicable laboratories time to ensure the accuracy of their data, followed by a 3-month data reporting period during which reporting entities will report applicable information to us. We believe this process will provide applicable laboratories adequate time to understand and prepare for the submission of the required data.

***Comment**:* Some commenters noted that accidental errors are inevitable with a new, first-of-its-kind, untested laboratory price reporting system, and the associated fines are significant. These commenters also opined that the new reporting requirements will require significant changes for the

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clinical laboratory community to undertake with no funding provided to make those changes, and that implementation of this law is being fast-tracked, which will lead to mistakes and unexpected problems.

Response: As discussed in section II.D.3 of this final rule, we are moving the implementation date of section 1834A of the Act to January 1, 2018. We expect applicable laboratories will have sufficient time to review their data for accuracy and completeness during the 6-month time period we are affording between the end of the data collection period and the beginning of the data reporting period. We recognize that there is a cost associated with the development and submission of data under section 1834A of the Act, but we believe this data submission process is an essential mechanism to establish fair and accurate Medicare payment rates for CDLTs. We are proceeding with implementation of the new reporting requirements in accordance with the statutory requirements, notwithstanding the new implementation date of January 1, 2018.

2. Data Certification

Section 1834A(a)(7) of the Act requires that an officer of each laboratory must certify the accuracy and completeness of the reported information required by section 1834A(a) of the Act. We proposed to implement this provision by requiring in § 414.504(d) that the President, CEO, or CFO of an applicable laboratory or an individual who has been delegated authority to sign for, and who reports directly to, the laboratory's President, CEO, or CFO, must sign a certification statement and be responsible for assuring that the applicable information provided is accurate, complete, and truthful, and meets all the reporting parameters. We stated that we would specify the processes for certification in subregulatory guidance prior to January 1, 2016.

A discussion of the comments we received on this topic, and our responses to those comments, appears below.

Comment: A few commenters objected to our plan to specify the processes for certification in subregulatory guidance prior to January 1, 2016, stating that some of these process issues need to be resolved in the final rule before subregulatory guidance is issued. Others have asked that the subregulatory guidance be issued as soon as possible.

Response: We will issue subregulatory guidance specifying the certification process for the submission of applicable information following publication of this final rule. As discussed in section II.D.3 of this final rule, we are moving the implementation date of the revised CLFS to January 1, 2018, so we now expect to issue the subregulatory guidance prior to January 1, 2018.

Comment: Some commenters requested that CMS create a certification form for applicable laboratories that states that the information and statements submitted are accurate and complete to the best of the laboratory's knowledge and the submission is made in good faith.

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***Response**:* We appreciate the commenters' suggestion and will take it into consideration as we develop subregulatory guidance for the certification process following the publication of this final rule.

***Comment**:* Some commenters stated that most laboratory Presidents, CEOs, and CFOs are not personally familiar with the volume and private payor rates for each laboratory test their labs offer, and they should not be required to certify the accuracy of the data submitted. The commenter suggested that a laboratory officer should be responsible for certifying that the data submitted is accurate to the best of his or her knowledge.

***Response**:* We agree with the commenter and in accordance with the changes to the data reporting requirements in this final rule, we have revised § 414.504(d) to require the President, CEO, or CFO of the reporting entity or an individual who has been delegated authority to sign for, and who reports directly to, such an officer to certify the accuracy of the data submitted for the reporting entity.