Frequently Asked Questions
CMS 1621 F
Medicare Program--Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule

On June 17, 2016 CMS announced the release of its final rule implementing section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA) that will require reporting entities to report private payor rates paid to laboratories for lab tests, which will be used to calculate Medicare payment rates. This final rule also announces CMS' decision to move the implementation date for the private payor rate-based fee schedule to January 1, 2018. A compilation of frequently asked questions (FAQs) about the final rule and the CMS responses are provided below. Updated questions and responses have been annotated by red font. To go directly to a category of questions, please click on the category below.

Additional guidance regarding the private payor rate-based CLFS may be found on the CLFS website under the PAMA regulations tab via the following link: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html

Select: MLN SE1619 [PDF, 115KB] - Guidance to Laboratories for Data Collection and Reporting.

1. General Theme:

Q1.1. Why is CMS changing the CLFS?

A1.1. Section 216(a) of PAMA, which established section 1834A of the Social Security Act (the Act), requires changes to the process for pricing Clinical Diagnostic Laboratory Tests (CDLTs) under the Medicare clinical laboratory fee schedule (CLFS). Section 1834A of the Act requires CMS to implement the new rates under the revised CFLS beginning January 1, 2017; however, CMS is announcing an implementation date of January 1, 2018.

Q1.2. Why did CMS move the implementation date for the new CLFS to January 1, 2018?

A1.2. In response to public comments, CMS moved the implementation date of the new private payor rate-based CLFS to January 1, 2018 to allow laboratories sufficient time after the publication of the final rule to develop the information systems necessary to collect private payor rates and to review and verify the data collected to ensure their accuracy before reporting this information to CMS. It also provides laboratories time to perform their own end user testing prior to the first data reporting period. Moving the implementation date back by 1 year also allows for an independent validation and testing of the CMS system to which reporting entities will report applicable information and provides laboratories time to perform their own end-user testing prior to the first data reporting period.

Q1.3. What type of input will be sought from clinicians and technical experts?

A1.3. CMS will consult, as required by statute, with an external expert advisory panel, which may include molecular pathologists, clinical laboratory researchers, and individuals with expertise in clinical laboratory science or economics of clinical laboratory services. This advisory panel will provide input on the establishment of payment rates for new CDLTs, the factors used in determining coverage and payment processes for new CDLTs, and the application process for determining whether a test meets the requirements to be an advanced diagnostic laboratory test (ADLT) under the criterion in section 1834A(d)(5)(A) of the Act.

Q1.4. Will the annual public meeting continue to occur?

A1.4. The statute requires CMS to continue to convene the annual laboratory public meeting for purposes of receiving comments and recommendations, and data on which the recommendations are based. This meeting is typically held in July each year.

Q1.5. What are laboratories required to do?

A1.5. Under the new CLFS, applicable laboratories or "reporting entities" (as discussed later) will collect and report to CMS "applicable information" consisting of private payor rates for each test and the volume of tests paid at each rate, and the specific HCPCS codes associated with the test. CLFS payment amounts will be determined based on the weighted median private payor rate for a given laboratory test, with certain exceptions for new tests and a group of tests defined by statute as new ADLTs.

Q1.6. How will the payment amounts for new tests be determined?

A1.6. For a CDLT that is assigned a new or substantially revised HCPCS code on or after the date of enactment of PAMA (that is, April 1, 2014), and which is not a new ADLT, the statute specifies that payment for the test will be determined on the basis of a crosswalking methodology or a gapfilling process.

Q1.7. How will CMS establish a payment rate when no private payor rate data are reported for a test?

A1.7. If CMS receives no applicable information for a given CDLT or ADLT, CMS will use crosswalking or gapfilling to price the test.

Q1.8. What impact will these changes have on beneficiary cost-sharing for laboratory services?

A1.8. The changes to the CLFS will not have any impact on beneficiary cost-sharing for laboratory services. Coinsurance and deductibles generally do not apply to CDLTs (or ADLTs) paid under the CLFS.

2. Applicable Laboratories

Q2.1. How will laboratories be defined for purposes of determining an applicable laboratory under the new CLFS?

A2.1. A laboratory, (as defined in CMS's Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations), using its National Provider Identifier (NPI), is considered an applicable laboratory if more than 50 percent of its total Medicare revenues are received from payments under the CLFS and physician fee schedule (PFS).

Additionally, generally, an applicable laboratory would also have to receive at least $12,500 in Medicare revenues received for CLFS services during a data collection period to be an applicable laboratory. The $12,500 will not apply to certain laboratories with respect to the ADLTs they offer and furnish.

Q2.2. How is this final definition of applicable laboratory different from the proposed definition of applicable laboratory?

A2.2. We finalized the definition of applicable laboratory in terms of the NPI rather than the Taxpayer Tax Identification Number (TIN). Therefore, the "majority of Medicare revenues" threshold (i.e., more than 50 percent of Medicare revenues are received from the PFS and CLFS) and the low expenditure threshold (i.e., at least $12,500 in Medicare revenues are received from the CLFS) during a data collection period, are determined by and applied to the NPI level rather than the TIN level entity, which will collectively report for all its associated NPIs.

Q2.3. Will defining applicable laboratory at the NPI level (instead of at the TIN level) allow a hospital outreach laboratory to be an applicable laboratory?

A2.3. Yes. A primary benefit of defining applicable laboratory at the NPI level is that it will allow hospital outreach laboratories that independently enroll in Medicare and that have an NPI to be an applicable laboratory. For example, a hospital outreach laboratory, either currently enrolled in Medicare as an independent laboratory (in which case it would already have its own

NPI) or that obtains a unique NPI (separate from the hospital), and bills for its hospital outreach services (that is, services furnished to patients other than inpatients or outpatients of the hospital) using its unique NPI, could meet the definition of an applicable laboratory if the laboratory meets the "majority of Medicare revenues" threshold and exceeds the Medicare CLFS revenues above the low expenditure threshold.

Q2.4. How is CMS determining whether the "majority of Medicare revenues" for a laboratory are from the CLFS and/or the PFS?

A2.4. Applying the standard definition of majority, which is more than 50 percent, an NPI that is a laboratory (under the CLIA regulatory definition of laboratory) would meet the "majority of Medicare revenues" threshold if more than 50 percent of its total Medicare revenues are from the CLFS and/or the PFS during a data collection period.

Q2.5. Did CMS revise its proposed low expenditure threshold for purposes of defining applicable laboratory?

A2.5. Yes. We revised the low expenditure threshold amount consistent with the revisions made to the definition of applicable laboratory and the data collection period. The majority of Medicare revenues threshold will now be applied at the NPI level as opposed to the TIN level, and the data collection period will now be 6 months instead of a full calendar year. Under the final policy, CMS will exclude from the definition of applicable laboratory NPI-level entities that receive less than $12,500 from the CLFS during a data collection period. The final rule also specifies that an entity that does not meet the definition of applicable laboratory will not be permitted to report applicable information (private payor rates and volume data) to CMS. For information on the revised data collection period, see additional FAQs below.

Q2.6. Who is required to report data?

A2.6. As noted above, CMS finalized the definition of applicable laboratory at the NPI level, rather than the TIN level; however, CMS is retaining the TIN-level entity as the "reporting entity" (now defined separately from the applicable laboratory). As such, the TIN-level entity is responsible for reporting applicable information for all of its component NPI-level entities that meet the definition of an applicable laboratory.

Q2.7. Is voluntary reporting permitted for laboratories that do not meet the definition of applicable laboratory?

A2.7. Only applicable information of applicable laboratories may be reported. Applicable information may not be reported for an entity that does not meet the definition of applicable laboratory.

Q2.8. Will each NPI-level entity that is a CLIA-certified laboratory be required to report private payor rate and volume data to CMS?

A2.8. No. As discussed above, the TIN-level entity is the reporting entity. The reporting entity must report applicable information for all of its component NPI-level entities that meet the definition of an applicable laboratory. Applicable laboratories generally must receive at least $12,500 in Medicare CLFS revenues for laboratory services during a data collection period and receive more than 50 percent of their Medicare revenues from CLFS and PFS services during the data collection period.

Q2.9. Is CMS concerned with the administrative burden the reporting requirement places on laboratories?

A2.9. CMS finalized a low expenditure threshold to reduce the reporting burden on small laboratories. We expect that 95 percent of physician office laboratories and 55 percent of independent laboratories will not be required to report applicable information under our final low expenditure criterion.

Additionally, we believe requiring reporting entities to report data at the TIN level will be less administratively burdensome for the laboratory industry as compared to requiring data to be reported at the NPI level. We believe defining applicable laboratory at the NPI level but retaining the reporting requirement at the TIN level will result in the same applicable information being reported but will require reporting by fewer entities and, therefore, be less burdensome to the laboratory industry.

Q2.10. Do you expect that precluding more than half of all independent laboratories and approximately 95 percent of all physician office laboratories will distort the data that CMS receives to set private payor rates?

A2.10. No. Even though we are substantially reducing the number of physician offices and independent laboratories for which applicable information will be reported, we estimate those physician laboratories and independent laboratories for which applicable information must be reported account for 92 percent of CLFS spending on physician office laboratories and more than 99 percent of CLFS spending on independent laboratories.

Q2.11. How is an applicable laboratory defined for purposes of reporting applicable information to CMS?

A2.11. An applicable laboratory is defined as a CLIA certified laboratory (which includes a facility that receives a CLIA certificate of waiver) and, using its own billing NPI, meets the majority of Medicare revenues threshold (that is, greater than 50 percent of total Medicare revenues derived from the CLFS and or PFS) during the data collection period and low expenditure threshold (at least $12,500 in revenue only from the CLFS) during the data collection period.

Q2.12. In order to qualify as an applicable laboratory, does a laboratory have to be assigned its own unique NPI number (that is, the NPI is assigned only to a given laboratory) which then bills for its laboratory services only under its unique laboratory NPI?

A2.12. No, a laboratory could share an NPI with another laboratory or other supplier such as a physician's office or group practice. That is, although a laboratory must have its own NPI, the group practice could also be assigned the same NPI as the laboratory. In other words, the laboratory's NPI doesn't have to be unique to the laboratory. If the laboratory and group practice are both assigned the same NPI and the group practice bills for its laboratory's services, then in essence, the laboratory's services are being billed under its own NPI. Example 4 from Medicare Learning Network article SE1619 is an example of a scenario wherein the laboratory and physician office are assigned the same NPI.

This example is provided below.

> *Example 4: An entity consists of five physician offices and one CLIA-certified laboratory. All five physician offices and the CLIA-certified laboratory are assigned the same NPI and bill for services under the same NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied based on the combined revenues of all components of the entity that bill for services under the same NPI. In other words, since the physician offices and CLIA-certified laboratory all have the same NPI and bill Medicare Part B under the same NPI, the entity is considered a single laboratory for purposes of applying the majority of Medicare revenues threshold and low expenditure threshold.*

Q2.13. Can a laboratory qualify as an applicable laboratory if the laboratory and group practice are assigned different NPIs?

A2.13. If the group practice is assigned a different NPI (different from its laboratory) and the group practice bills for its laboratory's services under the group practice NPI, the laboratory's services are not being billed under the laboratory's own NPI. The laboratory does not qualify as an applicable laboratory if no services are billed to Medicare Part B under its own NPI because no revenues attributed to the NPI are assigned to the laboratory.

Q2.14. For determining whether a laboratory meets the majority of Medicare revenue threshold and low expenditure threshold, when the Medicare Learning Network article SE1619 refers to the "billing NPI" does it mean the individual physician's NPI (Box 24J on the claim), or the group NPI (box 33 on the claim)?

A2.14. The majority of Medicare revenues threshold and low expenditure threshold is applied to the laboratory's own billing NPI. As noted in a previous response, if the laboratory in the group practice is assigned the same NPI as the ordering provider's NPI, and the ordering provider's NPI is used to bill for the laboratory's services, the majority of Medicare revenues threshold and low expenditure threshold would be applied to the billing NPI (Item 33a on the CMS-1500).

However, if the laboratory has a different NPI from the billing NPI or if the laboratory has not been assigned an NPI, the laboratory does not qualify to be an applicable laboratory. In other words, in order to qualify to be an applicable laboratory, the CLIA certified laboratory must be assigned an NPI and have its services billed to Medicare Part B under that NPI.

Q2.15. If a physician's office practice that is assigned its own NPI and bills both its physician services and its laboratory services under its own NPI and not under a unique laboratory NPI, can the physician's office laboratory be considered an applicable lab?

A2.15. As discussed in a previous response, if the physician office practice and physician office laboratory are assigned different NPIs, the answer is no. In other words, if the laboratory is not assigned the same NPI as the physician office practice, and the physician office practice bills for laboratory services using the NPI of the physician office practice, the laboratory does not qualify to be an applicable laboratory.

Q2.16. Can a physician office laboratory qualify as an applicable laboratory if its laboratory services are billed using the NPI of the laboratory when the laboratory and physician's office practice are assigned different NPIs?

A2.16. Yes. If the laboratory's services are billed under the laboratory's NPI (and not the physician's office NPI), the laboratory could qualify as an applicable laboratory if the laboratory's NPI meets the majority of Medicare revenue threshold and low expenditure threshold.

Q2.17. Can a hospital laboratory that bills under the hospital's NPI ever be considered a potential applicable laboratory since it does not have its own NPI number?

A2.17. Yes. However, it is highly unlikely because the majority of Medicare revenues for the NPI will not be derived from the Medicare CLFS and or the Medicare PFS. Example 7 from the Medicare Learning Network article SE1619 is an example of this scenario.

This example is provided below.

> ***Example 7:*** *A CLIA-certified hospital laboratory that performs laboratory services primarily for its hospital inpatients and hospital outpatients has the* ***same NPI as the hospital****. Laboratory services performed for non-hospital patients are billed using the hospital's NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold are applied to the* ***NPI of the entire hospital****. In this circumstance, it is unlikely that the hospital laboratory qualifies as an applicable laboratory because the majority of Medicare revenues for the NPI are received from the Hospital Inpatient Prospective Payment System and/or Hospital Outpatient Prospective Payment System, not from the CLFS and/or PFS.*

Q2.18. Would a hospital outreach laboratory with its own billing NPI (separate from the hospital's NPI) qualify as an applicable laboratory?

A2.18. The majority of Medicare revenues threshold and low expenditure threshold would be applied to the **NPI of the hospital outreach laboratory** and not to the hospital's NPI. If the hospital outreach laboratory, by its own billing NPI, meets the majority of Medicare revenue threshold and low expenditure threshold, it would qualify as an applicable laboratory.

Q2.19. Would a hospital outreach laboratory (with its own NPI) that bills for its laboratory services to Medicare Part A be considered Medicare Part B revenue, and therefore part of the numerator for calculating the majority of Medicare revenues threshold?

A2.19. Yes, all revenues received from the CLFS and PFS are Medicare Part B revenues and would be included in the numerator for purposes of determining whether a laboratory meets the majority of Medicare revenues threshold. If the hospital outreach laboratory bills for services paid on the CLFS and PFS using the CMS 1450 to the A/B MAC (A), the revenues are paid from Part B.

Q2.20. Are laboratories in Rural Health Clinics or Federally Qualified Health Centers subject to the new data collection and reporting requirements under PAMA?

A2.20. Although RHCs and FQHCs are required to furnish certain laboratory services, laboratory services are not within the scope of the RHC or FQHC benefit and are not billed under the RHC or FQHC payment methodologies. Therefore, if the laboratory is CLIA certified, has its own NPI and its laboratory services are billed under the laboratory's own NPI, the laboratory must determine whether it qualifies as an applicable laboratory for purposes of reporting applicable information to CMS.

Q2.21. Should beneficiary deductible and coinsurance amounts be included in the numerator as well as the denominator of the majority of Medicare revenues threshold equation?

A2.21. With regard to determining whether a laboratory meets the majority of Medicare revenues threshold, we clarify that any applicable beneficiary cost sharing, for example, deductible and coinsurance, should be included in both the numerator (PFS revenues + CLFS revenues) and denominator (total Medicare revenues). Although laboratory services paid under the CLFS are generally not subject to a beneficiary deductible or coinsurance amount, many services paid under the PFS are subject to beneficiary deductible and coinsurance.

Q2.22. How are Medicare Advantage payments under Medicare Part C handled when determining whether a laboratory meets the majority of Medicare revenues threshold?

A2.22. Medicare Advantage payments under Medicare Part C refers to payments received from a Medicare Advantage Plan. Medicare Advantage plans are offered to Medicare beneficiaries by private insurance companies approved by Medicare that cover all of Part A and Part B (sometimes referred to as original Medicare). They may also offer extra coverage like vision, hearing, dental, and other health and wellness programs. Most Medicare Advantage plans also include Medicare prescription drug coverage (Part D). In other words, a Medicare Advantage Plan is another option Medicare beneficiaries have for obtaining Medicare coverage.

Therefore, any revenues received during a data collection period from a Medicare Advantage Plan would be included in determining total Medicare revenues for purposes of applying the majority of Medicare revenues threshold.

Q2.23. With regard to the majority of Medicare revenues threshold, should anesthesia payments be included in the PFS revenues or are they to be excluded from the calculation?

A2.23. PAMA requires that the majority of the laboratory's Medicare revenues be derived from sections 1848, 1833(h) and 1843A of the Social Security Act. The statutory authority for the anesthesia services fee schedule is section 1848(b)(2)(B) of the Social Security Act. Therefore, with regard to the application of the majority of Medicare revenues threshold, we clarify that payments under the anesthesia fee schedule should be included in both the numerator (CLFS revenues + PFS revenues) and the denominator (total Medicare revenues).

3. Applicable Information

Q3.1. What entity is responsible for collecting applicable information from private payors?

A3.1. CMS is not prescribing how reporting entities and applicable laboratories are to collect and prepare applicable information for submission. The TIN-level entity and its applicable laboratory entities will establish their own approach for ensuring that the TIN-level entity can report applicable information.

Q3.2. Is the applicable information provided to CMS considered confidential?

A3.2. The statute requires that CMS and its contractors may not disclose reported applicable information in a form that would identify a specific payor or laboratory, or prices charged or payments made to a laboratory, except as CMS determines necessary to implement section 1834A of the Act and to permit the Comptroller General, the Director of the CBO, the HHS OIG, MedPAC, or other law enforcement entities such as the Department of Justice to review the information.

Q3.3. What type of private payor data must be reported?

A3.3. The reporting entity must report applicable information for each CDLT furnished by its component applicable laboratories. Applicable information is the private payor rate for each test for which final payment has been made during the data collection period, the associated volume for each test, and the specific HCPCS code associated with the test. If an applicable laboratory has more than one payment rate for the same private payor for the same test, or more than one payment rate for different payors for the same test, the reporting entity will report each such payment rate and the volume for the test at each such rate.

Q3.4. How frequently must private payor data be reported to CMS?

A3.4. Reporting entities are required to report applicable information every three years for CDLTs, and every year for ADLTs, except for an ADLT in its initial data collection period (in which case a reporting entity will report by the end of the second quarter of the new ADLT initial period).

Q3.5. Will the private payor rates collected (and reported to CMS) include discounts?

A3.5. The private payor rates reported to CMS are required by statute to reflect all discounts, rebates, coupons, and other price concessions.

Q3.6. Does the entire claim (which may include multiple laboratory test codes) need to be paid in final in order for all tests on the claim to qualify as applicable information?

A3.6. The determination of final payment is made at the test code level, not the entire claim level. For example, if Test A and Test B are both included on the same claim and final payment was made during the data collection period for Test A, but not for Test B, the private payor data for Test A would be considered applicable information and would be reported to CMS. Private payor data for Test B would not be reported because final payment for Test B did not occur during the data collection period.

Q3.7. Some private payors may initially withhold a percentage of the allowed payment amount for laboratory tests. At the end of each quarter (or annually), the private payor may issue a lump sum check to the laboratory for the withheld amount if the laboratory has met certain quality standards. How should those lump sum payments be accounted for in reporting private payor data to CMS?

A3.7. As discussed in the Medicare Learning Network article SE1619 entitled "Medicare Part B Clinical Laboratory Fee Schedule: Guidance to Laboratories for Collecting and Reporting Data for the Private Payor Rate-Based Payment System" 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; and (3) The associated volume for each test.

If the private payor makes a final payment for a laboratory test (identified by a specific HCPCS code) during the data collection period, the private payors rate for the test would be considered applicable information. Therefore, the reporting entity would report the HCPCS code for the test, that is, 100 percent of the private payors fee schedule amount (allowed amount) and the associated volume paid at that amount.

In circumstances where the private payor makes a preliminary payment for a specific HCPCS code (at less than the private payors full allowed amount), then subsequently makes a "final" lump sum payment (identified by the specific HCPCS code) during the data collection period, as noted above, the reporting entity would report the HCPCS code for the test, 100 percent of the private payors fee schedule amount (allowed amount) and the associated volume paid at that amount.

However, if (because of the private payors "lump sum" payment), the final private payor rate amount paid by HCPCS code and the associated volume paid at that final rate cannot be determined, the payment amount is not a private payor rate for purposes of applicable information and therefore is not reported to CMS.

In general, if because of how the private payor makes payment for a test or group of tests, a laboratory cannot correlate a private payors final payment amount and the associated volume paid at that rate to a specific HCPCS code, that amount is not a private payor rate for purposes of applicable information and would not be reported to CMS.

Q3.8. For purposes of reporting private payor data to CMS, should the reporting entity include data where the primary private payor has reimbursed the laboratory, but the secondary payor or the patient has not paid their portion? In other words, must laboratory test codes be in a "final state" (that is, completely paid by all parties) before they are included as applicable information?

A3.8. As noted in a previous response, 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; and (3) the associated volume for each test.

For purposes of applicable information, the private payor rate for a test code should include any patient cost sharing responsibilities required by the private payor (for instance, patient deductible and/or coinsurance amounts) and payments due from a secondary insurer and or collection agency. In other words, the private payor rate is 100 percent of the private payors fee schedule amount for the test. For example, if the private payors fee schedule (e.g. allowable amount) is $150 and the private payors final claims paid amount of $130 was received during the data collection period, and the patient's responsibility of $20 was not received until after the data collection period, the reporting entity should report a private payor rate of $150 for the test(s).

The important concept here is that if the primary private payors final paid claim for a laboratory test code is made during the data collection period, the reporting entity reports the HCPCS code, 100 percent of the private payors fee schedule amount for the test (the allowed amount) and the associated volume paid at that amount.

4. Data Collection Period

Q4.1. What is the data collection period and time frame for reporting private payor data to CMS?

A4.1. CMS revised its proposed data collection period from a full calendar year to 6 months. Except for a new ADLT in its initial data collection period, the data collection period will be the January 1 through June 30 period preceding the next data reporting period. The data reporting period was finalized as proposed. Applicable information will be reported for a data collection period between the January 1 through March 31 data reporting period.

Q4.2. What is the purpose of the 6-month window between the end of the data collection period and beginning of the data reporting period?

A4.2. CMS finalized a 6-month period of time between the end of the data collection period and the beginning of the data reporting period to provide an opportunity for laboratories and reporting entities to review and validate applicable information to ensure the data are complete and accurate before it is reported to CMS.

5. Penalties

Q5.1. Does the law include any penalties for non-reporting?

A5.1. The statute authorizes CMS to impose civil monetary penalties of up to $10,000 per day, adjusted for inflation as required by the Inflation Adjustment Act Improvements Act of 2015, for each failure to report or each misrepresentation or omission in reporting applicable information. Additional guidance on reporting will be issued after publication of the CLFS final rule.

6. Advanced Diagnostic Laboratory Tests (ADLTs)

Q6.1. What is an advanced diagnostic laboratory test (ADLT)?

A6.1. PAMA defines ADLTs as: "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."

Q6.2. Did CMS revise any proposed requirements for tests qualifying as an ADLT under criterion (A)?

A6.2. Yes. CMS revised the requirements under criterion A of the definition of an ADLT to include tests that are solely comprised of proteins. Under the final rule, tests solely comprised of proteins may qualify for ADLT status under criterion A. We also removed the proposed requirement that the test must be a molecular pathology analysis. All other requirements under criterion A were finalized as proposed. Under our final policy, a test qualifying as an ADLT under criterion A: (i) is an analysis of multiple biomarkers of DNA, RNA, or proteins; (ii) when combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition or respond to a particular therapy or therapies; (iii) provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and (iv) may include other assays.

CMS will require laboratories to submit documentation to support their application for ADLT status, including evidence of their empirically derived algorithms and how their test provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests.

Q6.3. Did CMS finalize its proposal to define a single laboratory (for purposes of an ADLT) as a single CLIA certificate?

A6.3. No. CMS did not adopt its proposal to define a single laboratory as a single CLIA certificate. For purposes of an ADLT, we revised the definition of a single laboratory to mean a laboratory (as defined under the CLIA regulatory definition of a laboratory) that furnishes the test, and that may also design, offer, or sell the test. The definition also includes the entities that own the laboratory and the entities that are owned by the laboratory; such entities may design, offer or sell the test. Under our final definition of single laboratory, a corporate entity that owns multiple laboratories could furnish a new ADLT at each laboratory site. It also enables other parts of the single laboratory organization to be involved with aspects of the ADLT, such as research and development. However, only the laboratory parts of the single laboratory organization may perform the test. Additionally, our definition of single laboratory will allow an original developing laboratory that meets the definition of a single laboratory to continue to be a single laboratory if it chooses to expand its organization by acquiring new laboratory sites to meet increased demand for laboratory testing.

Q6.4. Will the single laboratory offering and furnishing an ADLT need to meet the "low expenditure threshold" in order to report applicable information?

A6.4. If the single laboratory offering and furnishing an ADLT does not receive at least $12,500 in Medicare revenues from CLFS services during a data collection period, but otherwise meets the definition of applicable laboratory (including that it receives more than 50 percent of its Medicare revenues from PFS and CLFS services during the data collection period), it would be an applicable laboratory but only for purposes of its ADLTs, not for other CDLTs the laboratory may furnish. With respect to other CDLTs the single laboratory furnishes (if any) that are not ADLTs, the low expenditure threshold still applies.

Q6.5. Can the single laboratory offering and furnishing an ADLT report applicable information for its CDLTs that are not ADLTs if it doesn't meet the low expenditure threshold?

A6.5. No. The single laboratory offering and furnishing an ADLT that does not receive at least $12,500 in Medicare CLFS revenues is not an applicable laboratory with respect to its CDLTs that are not ADLTs, and its applicable information for those other CDLTs may not be reported.

Q6.6. How is CMS defining "successor owner" for purposes of an ADLT?

A6.6. A successor owner for purposes of an ADLT means a single laboratory, which has assumed ownership of the laboratory that designed the test or of the single laboratory that is a

successor owner to the single laboratory that designed the test, through a partnership, unincorporated sole proprietorship; or corporation.

Q6.7. Can there be a successor owner to a successor owner?

A6.7. Yes. Successor ownership is not limited to just the successor of the original developing laboratory. There can be successor owners to successor owners.

Q6.8. Why did CMS remove "leasing" from the proposed definition of successor owner?

A6.8. For changes in ownership resulting from leasing, we proposed that the lease of all or part of the single laboratory organization would constitute a change in ownership of the leased portion. However, since each successor owner is an entity that assumes ownership of a single laboratory, the successor owner becomes the owner of the entire single laboratory organization, that is, the laboratory and the other entities the laboratory owns or is owned by. As such, leasing a portion of a single laboratory does not comport with our final policy that a single laboratory includes the laboratory and the other entities that own or are owned by the laboratory. Therefore, we removed leasing from the definition of successor owner as a circumstance under which there can be a successor owner.

Q6.9. How will payment for new ADLTs be determined under the new CLFS?

A6.9. New ADLTs will be paid using their actual list charge during the new ADLT initial period, which is a period of three full calendar quarters. The actual list charge is defined as the publicly available rate on the first day the new ADLT is obtainable by a patient who is covered by private insurance, or marketed to the public as a test a patient can receive, even if the test has not yet been performed on that date.

Q6.10. When does the new ADLT initial period begin?

A6.10. CMS revised its proposed start date of the new ADLT initial period. Under our final policy, the new ADLT initial period will begin on the first day of the first full calendar quarter following the later of the date a Medicare Part B coverage determination is made or the date ADLT status is granted by CMS for the test. For example, if the test is covered under Medicare Part B on February 15 and CMS grants ADLT status for the test on March 10, the new ADLT initial period would begin on April 1 and end December 31.

Q6.11. How will the payment amount be determined for new ADLTs prior to the new ADLT initial period?

A6.11. The local Medicare Administrative Contractor (MAC) will determine the payment amount for a new ADLT prior to the new ADLT initial period. Using the example from the preceding question, the local Part B MAC will determine the payment amount for the new ADLT from February 15 through March 31. Once the new ADLT initial period begins, payment for the new ADLT will be the actual list charge amount.

Q6.12. How will payment for ADLTs be determined after the new ADLT initial period is over?

A6.12. Applicable information for new ADLTs must be reported to CMS no later than the last day of the second quarter of the new ADLT initial period. The payment amount determined using the weighted median methodology will apply after the new ADLT initial period and will continue to apply until the year following the next data collection period. In other words, CMS will pay a new ADLT's actual list charge amount during the new ADLT initial period. Once the new ADLT initial period is over, payment for a new ADLT will be based on the applicable information (i.e., private payor rates) reported to CMS.

Q6.13. How frequently must private payor rates be collected and reported to CMS for ADLTs?

A6.13. Applicable information for ADLTs must be collected annually from January 1 through June 30, and reported to CMS during the data reporting period, which is January 1 through March 31, following the data collection period.

Q6.14. Did CMS make any revisions to the recoupment provision for new ADLTs if actual list charge exceeds the market rate?

A6.14. Yes. If the statutory recoupment threshold is reached for a new ADLT, meaning, when the actual list charge is greater than 130 percent of the weighted median private payor rate calculated using applicable information collected during the new ADLT initial period, CMS will recoup the difference between the actual list charge and 130 percent of the weighted median private payor rate. If the actual list charge amount is less than the recoupment threshold (that is, not greater than 130 percent of the weighted median private payor rate amount), the recoupment provision will not apply.

Q6.15. How is CMS' final ADLT recoupment policy different from its proposed recoupment policy?

A6.15. Under our proposed policy, if the ADLT's actual list charge exceeds the weighted median private payor rate determined during the new ADLT initial period by more than 130 percent, we would have recouped the entire difference between the actual list charge and the weighted median private payor rate. Under our final policy, we will only recoup the difference between 130 percent of the ADLT's weighted median private payor rate and its actual list charge. In other words, we will pay for ADLTs during the new ADLT initial period up to 130 percent of the weighted median private payor rate determined from applicable information collected and reported during the new ADLT initial period.

7. Payment Reduction Limitation

Q7.1. Does PAMA limit the amount of payment reduction for existing laboratory tests?

A7.1. Section 1834A(b)(3) of the Act limits the reduction of the payment amount for an existing test as compared to the payment amount for the preceding year. For the first three years after implementation, the statute limits the reduction to 10 percent per year, and to 15 percent per year for the following three years. CMS finalized the payment reduction limit to correspond to the January 1, 2018 implementation of the revised private payor rate-based CLFS. The 10 percent payment reduction limit will apply for CY 2018 through CY 2020, and the 15 percent payment reduction limit will apply for CY 2021 through CY 2023. The phased-in payment amount limit per year for existing tests paid under the CLFS prior to January 1, 2018 will be applied using the 2017 national limitation amount (NLA) for the existing test as the baseline payment amount. To determine the application of the phased-in payment reduction limit for a test, the weighted median private payor rate calculated for CY 2018 will be compared to the CY 2017 NLA.

Q7.2. Will the maximum 10 percent (or 15 percent) reduction be applied to the prior year's payment rate?

A7.2. Yes, the maximum reduction will be applied to the prior year's payment rate until the reduction becomes less than 10 percent for each of CYs 2018 through 2020 (or 15 percent for each of CYs 2021 through 2023). For example, if an existing test under the CLFS for CY 2017 has a payment rate of $20.00, but the weighted median private payor rate calculated during CY 2017 for CY 2018 (using January 1, 2016 through June 30, 2016 data) produces a payment rate of $15.00, then for CY 2018, the payment rate for the test becomes $18.00 ($20.00 minus $2.00), which reflects the maximum 10 percent allowed reduction of the current payment amount. The following year, a 10 percent reduction would equal $1.80, lowering the total payment to $16.20. This process would continue to apply to the prior year's payment until the reduction becomes less than the applicable percentage (10 percent or 15 percent), after which the fee schedule payment will reflect the weighted median of the private payor rates for the test (in this example, $15.00).

8. Coding

Q8.1. What type of code will be used to identify new and existing ADLTs and new and existing CDLTs (that are not ADLTs) that are cleared or approved by the FDA?

A8.1. The AMA is creating a new coding process specifically to meet the requirements of PAMA. Either the AMA will create CPT codes or CMS will create HCPCS level II codes to identify new and existing ADLTs and new and existing CDLTs (that are not ADLTs) that are cleared or approved by the FDA.

Q8.2. How will CMS establish a unique identifier for purposes of tracking and monitoring ADLTs or CDLTs that are cleared or approved by the FDA if requested by a laboratory or manufacturer?

A8.2. If a laboratory or manufacturer specifically requests a unique identifier for tracking and monitoring an ADLT or an FDA-approved or cleared CDLT, CMS will assign the test a unique HCPCS code if it does not already have one.