2018 extended these policies through 2019. Furthermore, section 3(b) of the PAMPA requires the Secretary of Health and Human Services to submit to Congress a report on the development of an episodic APM for payment under the Medicare program under title XVIII of the Act for radiation therapy (RT) services furnished in non-facility settings (''Report to Congress''). In the Report to Congress [7] delivered in November 2017, we discussed the current status of RT services and payment, and reviewed model design considerations for a potential APM for RT services.

For the Report to Congress, the CMS Center for Medicare and Medicaid Innovation (Innovation Center) conducted an environmental scan of current evidence, as well as held a public listening session followed by an opportunity for RT stakeholders to submit written comments about a potential APM. A review of the applicable evidence in the Report to Congress demonstrated that episode payment models can be a tool for improving care and reducing expenditures. We believe that radiation oncology is a promising area of health care for bundled payments, in part, based on the findings in the Report to Congress. The CMS Innovation Center has and will continue to use public information regarding commercial initiatives, as well as stakeholder feedback to help inform the development, implementation, and refinement of design and testing of a potential model that tests payment for RT services under the authority of section 1115A of the Act.

III. Other Provisions of the Proposed Rule

A. Clinical Laboratory Fee Schedule

1. Background

Prior to January 1, 2018, Medicare paid for clinical diagnostic laboratory tests (CDLTs) on the Clinical Laboratory Fee Schedule (CLFS) under sections 1832, 1833(a), (b), and (h), and 1861 of the Social Security Act (the Act). Under the previous methodology, CDLTs were paid based on the lesser of: (1) The amount billed; (2) the local fee schedule amount established by the Medicare Administrative Contractor (MAC); or (3) a national limitation amount (NLA), which is a percentage of the median of all the local fee schedule amounts (or 100 percent of the median for new tests furnished on or after January 1, 2001). In practice, most tests were paid at the NLA. Under the previous system, the CLFS amounts were updated for inflation based on the percentage change in the Consumer Price Index for All Urban Consumers (CPI–U), and reduced by a multi-factor productivity adjustment and other statutory adjustments, but were not otherwise updated or changed.

Section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for CDLTs under the CLFS. The CLFS final rule, entitled Medicare Clinical Diagnostic Laboratory Tests Payment System (CLFS final rule), published in the **Federal Register** on June 23, 2016, implemented section 1834A of the Act. Under the CLFS final rule, ''reporting entities'' must report to CMS during a ''data reporting period'' ''applicable information'' collected during a ''data collection period'' for their component ''applicable laboratories.'' Applicable information is defined at § 414.502 as, with respect to each CDLT for a data collection period: Each private payor rate for which final payment has been made during the data collection period; the associated volume of tests performed corresponding to each private payor rate; and the specific Healthcare Common Procedure Coding System (HCPCS) code associated with the test. Applicable information does not include information about a test for which payment is made on a capitated basis. An applicable laboratory is defined at § 414.502, in part, as an entity that is a laboratory (as defined under the Clinical Laboratory Improvement Amendments (CLIA) definition at § 493.2) that bills Medicare Part B under its own National Provider Identifier (NPI). In addition, an applicable laboratory is an entity that receives more than 50 percent of its Medicare revenues during a data collection period from the CLFS and/or the Physician Fee Schedule (PFS). We refer to this component of the applicable laboratory definition as the ''majority of Medicare revenues threshold.'' The definition of applicable laboratory also includes a ''low expenditure threshold'' component which requires an entity to receive at least $12,500 of its Medicare revenues from the CLFS for its CDLTs that are not advanced diagnostic laboratory tests (ADLTs).

The first data collection period, for which applicable information was collected, occurred from January 1, 2016 through June 30, 2016. The first data reporting period, during which reporting entities reported applicable information to CMS, occurred January 1, 2017 through March 31, 2017. On March 30, 2017, we announced a 60-day enforcement discretion period of the assessment of civil monetary penalties (CMPs) for reporting entities that failed to report applicable information. Additional information about the 60-day enforcement discretion period is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/2017-March-Announcement.pdf*.

In general, the payment amount for each CDLT on the CLFS furnished beginning January 1, 2018, is based on the applicable information collected during the data collection period and reported to us during the data reporting period, and is equal to the weighted median of the private payor rates for the test. The weighted median is calculated by arraying the distribution of all private payor rates, weighted by the volume for each payor and each laboratory. The payment amounts established under the CLFS are not subject to any other adjustment, such as geographic, budget neutrality, or annual update, as required by section 1834A(b)(4)(B) of the Act. Additionally, section 1834A(b)(3) of the Act, implemented at § 414.507(d), provides a phase-in of payment reductions, limiting the amounts the CLFS rates for each CDLT (that is not a new ADLT or new CDLT) can be reduced as compared to the payment rates for the preceding year. For the first 3 years after implementation (CY 2018 through CY 2020), the reduction cannot be more than 10 percent per year, and for the next 3 years (CY 2021 through CY 2023), the reduction cannot be more than 15 percent per year. For most CDLTs, the data collection period, data reporting period, and payment rate update occur every 3 years. As such, the next data collection period for most CDLTs will be January 1, 2019 through June 30, 2019, and the next data reporting period will be January 1, 2020 through March 31, 2020, with the next update to CLFS occurring on January 1, 2021. Additional information on the private payor rate-based CLFS is detailed in the CLFS final rule (81 FR 41036 through 41101).

2. Recent Stakeholder Feedback

As we discussed in the CY 2019 PFS proposed rule (83 FR 35856), after the initial data collection and data reporting periods, we received feedback on a range of topics related to the private payor rate-based CLFS. Some commenters expressed concern that the

[7] Report to Congress: Episodic Alternative Payment Model for Radiation Therapy Services. *https://innovation.cms.gov/Files/reports/radiationtherapy-apm-rtc.pdf*.

CY 2018 CLFS payments rates are based on applicable information from only a relatively small number of laboratories. Some commenters stated that, because most hospital-based laboratories were not applicable laboratories, and therefore, did not report applicable information during the initial data reporting period, the CY 2018 CLFS payment rates do not reflect their information and are inaccurate. Other commenters were concerned that the low expenditure threshold excluded most physician office laboratories and many small independent laboratories from reporting applicable information.

We noted in the proposed rule that, in determining payment rates under the private payor rate-based CLFS, one of our objectives is to obtain as much applicable information as possible from the broadest possible representation of the national laboratory market on which to base CLFS payment amounts, for example, from independent laboratories, hospital outreach laboratories, and physician office laboratories, without imposing undue burden on those entities. As we noted throughout the CLFS final rule, we believe it is important to achieve a balance between collecting sufficient data to calculate a weighted median that appropriately reflects the private market rate for a CDLT, and minimizing the reporting burden for entities. In response to this feedback and in the interest of facilitating our goal, we proposed a change to the Medicare CLFS for CY 2019 in section III.A. of the CY 2019 PFS proposed rule. We stated that we believe this proposal may result in more data being used on which to base CLFS payment rates.

In addition to this proposal, we solicited public comments on other approaches that have been requested by some stakeholders who suggested that such approaches would result in CMS receiving even more applicable information to use in establishing CLFS payment rates. The approaches include revising the definition of applicable laboratory and changing the low expenditure threshold. These topics are discussed in this section.

3. Change to the Majority of Medicare Revenues Threshold in Definition of Applicable Laboratory

In order for a laboratory to meet the majority of Medicare revenues threshold, section 1834A(a)(2) of the Act requires that, ''with respect to its revenues under this title, a majority of such revenues are from'' the CLFS and the PFS in a data collection period. In the CLFS final rule, we stated that ''revenues under this title'' are payments received from the Medicare program, which includes fee-for-service payments under Medicare Parts A and B, as well as Medicare Advantage (MA) payments under Medicare Part C, and prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance amounts for Medicare services furnished during the data collection period (81 FR 41043). This total Medicare revenues amount (the denominator in the majority of Medicare revenues threshold calculation) is compared to the total of Medicare revenues received from the CLFS and/or PFS (the numerator in the majority of Medicare revenues threshold calculation). If the numerator is greater than 50 percent of the denominator for a data collection period, the entity has met the majority of Medicare revenues threshold criterion. We reflected that requirement in § 414.502 in the third paragraph of the definition of applicable laboratory.

As we explained in the CY 2019 PFS proposed rule, we have considered that our current interpretation of total Medicare revenues may have the effect of excluding laboratories that furnish Medicare services to a significant number of beneficiaries enrolled in MA plans under Medicare Part C from meeting the majority of Medicare revenues threshold criterion, and therefore, from qualifying as applicable laboratories. For instance, if a laboratory has a significant enough Part C component so that it is receiving greater than 50 percent of its total Medicare revenues from MA payments under Part C, it would not meet the majority of Medicare revenues threshold because its revenues derived from the CLFS and/or PFS would not constitute a majority of its total Medicare revenues. We stated that we believe if we were to exclude MA plan revenues from total Medicare revenues, more laboratories of all types may meet the majority of Medicare revenues threshold, and therefore, the definition of applicable laboratory, because it would have the effect of decreasing the amount of total Medicare revenues and increase the likelihood that a laboratory's CLFS and PFS revenues would constitute a majority of its Medicare revenues.

We stated in the proposed rule that we believe section 1834A of the Act permits an interpretation that MA plan payments to laboratories not be included in the total Medicare revenues component of the majority of Medicare revenues threshold calculation. Rather, MA plan payments to laboratories can be considered to only be private payor payments under the CLFS. We emphasized in the CY 2019 PFS proposed rule that this characterization of MA plan payments is limited to only the CLFS for purposes of defining applicable laboratory. Whether MA plan payments to laboratories or other entities are considered Medicare ''revenues'' or ''private payor payments'' in other contexts in the Medicare program is not relevant to our proposal, and our characterization of MA plan payments as private payor payments for purposes of the CLFS has no bearing on any aspect of the Medicare program other than the CLFS.

As noted above, we defined total Medicare revenues for purposes of the majority of Medicare revenues threshold calculation to include fee-for-service payments under Medicare Parts A and B, as well as MA payments under Medicare Part C, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance amounts for Medicare services furnished during the data collection period. However, section 1834A(a)(8) of the Act, which defines the term ''private payor,'' identifies at section 1834A(a)(8)(B) a ''Medicare Advantage plan under Part C'' as a type of private payor. Under the private payor rate-based CLFS, CLFS payment amounts are based on private payor rates that are reported to CMS. Accordingly, an applicable laboratory that receives MA plan payments is to consider those MA plan payments in identifying its applicable information, which must be reported to CMS. We explained in the proposed rule that we believe it is more logical to not consider MA plan payments under Part C to be both Medicare revenues for determining applicable laboratory status and private payor rates for purposes of reporting applicable information. Congress contemplated that applicable laboratories would furnish MA services, as reflected in the requirement that private payor rates must be reported for MA services. However, under our current definition of applicable laboratory, laboratories that furnish MA services, particularly those that furnish a significant amount, are less likely to meet the majority of Medicare revenues threshold, which means they would be less likely to qualify as applicable laboratories, and as a result, to report private payor rates for MA services.

Therefore, we stated in the proposed rule that after further review and consideration of the new private payor rate-based CLFS, we believe it is appropriate to include MA plan revenues as only private payor payments rather than both Medicare revenues, for the purpose of

determining applicable laboratory status, and private payor payments, for the purpose of specifying what is applicable information. Such a change would have the effect of eliminating the laboratory revenue generated from a laboratory's Part C-enrolled patient population as a factor in determining whether a majority of the laboratory's Medicare revenues are comprised of services paid under the CLFS or PFS. We noted that we believe this change would permit a laboratory with a significant Medicare Part C revenue component to be more likely to meet the majority of Medicare revenues threshold and qualify as an applicable laboratory. In other words, MA payments are currently included as total Medicare revenues (the denominator). In order to meet the majority of Medicare revenues threshold, the statute requires a laboratory to receive the majority of its Medicare revenues from the CLFS and or PFS. If MA plan payments were excluded from the total Medicare revenues calculation, the denominator amount would decrease. If the denominator amount decreases, the likelihood increases that a laboratory would qualify as an applicable laboratory. Therefore, we stated that we believe this proposal responds directly to stakeholders' concerns regarding the number of laboratories for which applicable information must be reported because a broader representation of the laboratory industry may qualify as applicable laboratories, which means we would receive more applicable information to use in setting CLFS payment rates.

For these reasons, we proposed that MA plan payments under Part C would not be considered Medicare revenues for purposes of the applicable laboratory definition. We noted in the CY 2019 PFS proposed rule that if finalized, we would revise paragraph (3) of the definition of applicable laboratory at § 414.502 accordingly. We reiterated that not characterizing MA plan payments under Medicare Part C as Medicare revenues would be limited to the definition of applicable laboratory under the CLFS, and would not affect, reflect on, or otherwise have any bearing on any other aspect of the Medicare program.

In an effort to provide stakeholders a better understanding of the potential reporting burden that may result from this proposal, we provided a summary of the distribution of data reporting that occurred for the first data reporting period. We explained that if we were to finalize the proposed change to the majority of Medicare revenues threshold component of the definition of applicable laboratory, additional laboratories of all types serving a significant population of beneficiaries enrolled in Medicare Part C could potentially qualify as applicable laboratories, in which case their data would be reported to us. As discussed in the proposed rule, we received over 4.9 million records from 1,942 applicable laboratories for the initial data reporting period, which we used to set CY 2018 CLFS rates. Additional analysis shows that the average number of records reported for an applicable laboratory was 2,573. The largest number of records reported for an applicable laboratory was 457,585 while the smallest amount was 1 record. A summary of the distribution of reported records from the first data collection period is illustrated in the Table 25.

TABLE 25—SUMMARY OF RECORDS REPORTED FOR FIRST DATA REPORTING PERIOD

[By applicable laboratory]

Total records	Average records	Min records	Max records	Percentile distribution of records				
				10th	25th	50th	75th	90th
4,995,877	2,573	1	457,585	23	79	294	1,345	4,884

Assuming a similar distribution of data reporting for the next data reporting period, the mid-point of reported records for an applicable laboratory would be approximately 300 (50th percentile for the first data reporting period was 294). However, as illustrated in Table 25, the number of records reported varies greatly, depending on the volume of services performed by a given laboratory. Laboratories with larger test volumes, for instance at the 90th percentile, should expect to report more records as compared to the midpoint used for this analysis. Likewise, laboratories with smaller test volume, for instance at the 10th percentile, should expect to report fewer records as compared to the midpoint.

The following is a summary of the comments we received and our responses to the comments regarding our proposal to modify the definition of applicable laboratory to exclude MA plan payments under Part C as Medicare revenues.

Comment: Many commenters supported CMS' proposal to exclude MA plan payments under Part C from total Medicare revenues and agreed it would help achieve CMS' goal of increasing the number of laboratories reporting applicable information. They stated that by excluding MA plan payments from total Medicare revenues, the denominator of the majority of Medicare revenues threshold, more laboratories of all types with a significant share of revenues from Medicare Part C would be more likely to qualify as an applicable laboratory and report applicable information to CMS. They also agreed that removal of MA plan payments from total Medicare revenues is consistent with the statute, which defines MA plans as a private payor, and therefore will help enable more laboratories to qualify as applicable laboratories. The commenters that supported excluding MA plan payments under Part C from total Medicare revenues urged CMS to finalize the proposal. However, some stakeholders objected to CMS' proposal because it would result in administrative reporting burden for additional laboratories without having a perceptible impact on CLFS rates (because the largest laboratories with the highest test volumes will continue to dominate the weighted median of private payor rates). They stated that increasing the number of laboratories qualifying for applicable laboratory status and imposing additional data reporting burden, with no perceptible impact expected on the CLFS rates, is in direct conflict with the Administration's goal of reducing regulatory burden.

Response: As discussed in the proposed rule, including MA plan payments as total Medicare revenues in the majority of Medicare revenues threshold (as we currently do) dilutes the percentage of total Medicare revenues attributed to CLFS and PFS revenues. As a result, laboratories performing tests for a significant Medicare Part C population are less likely to qualify as an applicable

laboratory and, therefore, to report applicable information to us.

For the additional data reporting burden, as discussed in the Regulatory Impact Analysis in section VII. of the proposed rule (83 FR 36048), we estimated that excluding MA plan payments from total Medicare revenues (the denominator) of the majority of Medicare revenues threshold, and keeping the numerator constant (that is, revenues from only the CLFS and or PFS) yielded an increase of 49 percent in the number of laboratories meeting the majority of Medicare revenues threshold.

We also noted in the proposed rule that there would only be an associated impact to the Medicare rates to the extent the additional applicable laboratories are paid at a higher (or lower) private payor rate, as compared to other laboratories that reported previously *and* to the extent the volume of services performed by these additional applicable laboratories is significant enough to make an impact on the weighted median of private payor rates. Given that the largest laboratories with the highest test volumes dominate the weighted median of private payor rates, and the largest laboratories reported data for the determination of CY 2018 CLFS rates and are expected to report again, we stated that we do not expect the additional reported data resulting from our proposed change to the majority of Medicare revenues threshold to have a predictable, direct impact on CLFS rates. By this we mean that we cannot predict whether the additional applicable laboratories reporting applicable information are paid at a higher (or lower) private payor rate, as compared to other laboratories that reported previously and whether the private payor rate volume of services performed by these additional applicable laboratories is significant enough to make an impact on the weighted median of private payor rates.

However, as we noted in the proposed rule, our proposal to exclude MA plan payments from total Medicare revenues responded directly to stakeholder concerns regarding the number of applicable laboratories reporting applicable information for the initial data reporting period. We believe that enabling more laboratories of all types that furnish testing to a significant Medicare Part C population to qualify as applicable laboratories and report data to CMS directly supports our goal of collecting as much applicable information as possible from the broadest representation of the national laboratory market on which to base CLFS payment amounts. Therefore, we believe receiving additional applicable information from more laboratories of all laboratory types outweighs the additional reporting burden on laboratories.

Comment: One commenter disagreed with CMS' proposal to define MA plan payments as private payor payments and not Medicare revenues for the purpose of determining applicable laboratory status. The commenter stated that MA plans are Medicare plans that rarely negotiate a rate that varies from the Medicare payment rate and that using MA plan payments to develop Medicare rates is simply a circular reference. The commenter also stated that Medicaid managed care plans should not be considered as a private payor because state Medicaid programs may set laboratory test rates at a percentage of the Medicare CLFS, for example, 80 percent of the Medicare CLFS rate. As such, the commenter stated that the use of Medicaid managed care plan data will create a ''downward spiral'' of CLFS rates.

Response: Sections 1834A(a)(8)(B) and (C) of the Act define a private payor to include a Medicare Advantage plan under Part C, and a Medicaid managed care organization (as defined in section 1903(m) of the Act), respectively. Therefore, the statute would not permit us to exclude a Medicare Advantage plan under Part C or a Medicaid managed care organization from the definition of private payor for the purposes of determining the applicable information reported to us from which to set CLFS rates. We understand the commenter's concern regarding the potential circularity of using Medicaid managed care and MA plan data to set Medicare CLFS rates to the extent that Medicaid managed care and MA plan rates are established based on Medicare rates. However, we note that section 1834A(a) of the Act explicitly directs us to use such data in setting the CLFS rates. For the suggestion that including Medicaid managed care plan data will result in a ''downward spiral,'' we note that the statute anticipates that rates will decrease under the new private payor rate-based CLFS and provides a phase-in of payment reductions. Section 1834A(b)(3) of the Act, implemented at § 414.507(d), limits the amounts the CLFS rates for each CDLT (that is not a new ADLT or new CDLT) can be reduced as compared to the payment rates for the preceding year. For the first 3 years after implementation (CY 2018 through CY 2020), the reduction cannot be more than 10 percent per year, and for the next 3 years (CY 2021 through CY 2023), the reduction cannot be more than 15 percent per year. We also note that the Medicaid managed care plans may or may not be obligated to continue to use Medicare rates (or a reduction thereof) as a basis for their rates were such a ''downward spiral'' to occur.

Comment: One commenter urged CMS to conduct a more robust and transparent analysis of this proposal to identify the types of laboratories to which this policy would apply and the relative impact on payment rates. The commenter also requested that CMS release the number of clinical laboratories that previously reported applicable information, based on market segment and geographic locations. The commenter asserted that without such information, it would be premature to implement a proposal that will only increase administrative burden on hospitals and other organizations which will be forced to re-determine their applicable laboratory status.

Response: As discussed previously, our proposal to exclude MA plan payments from the total Medicare revenues for purposes of applying the majority of Medicare revenues threshold would affect laboratories of all types, that is hospital laboratories, large and small independent laboratories, and physician office laboratories that furnish services to a significant Medicare Part C enrollment population. We also explained that since the largest laboratories with the highest test volumes dominate the weighted median of private payor rates, and the largest laboratories reported data for the determination of CY 2018 CLFS rates and are expected to report again, we did not expect the additional reported data resulting from our proposed change to the majority of Medicare revenues threshold to have a predictable, direct impact on CLFS rates. As we noted previously, this means that we cannot predict whether the additional applicable laboratories reporting applicable information are paid at a higher (or lower) private payor rate, as compared to other laboratories that reported previously *and* whether the private payor rate volume of services performed by these ''additional'' applicable laboratories is significant enough to make an impact on the weighted median of private payor rates. However, we noted that we believe this proposal responded directly to stakeholder concerns regarding the number of applicable laboratories reporting applicable information for the initial data reporting period (83 FR 36049). We also noted that in the previous data reporting period we received applicable information from 1,942 applicable laboratories from every state, the District of Columbia, and

Puerto Rico, and that additional summary information regarding data reporting for the Medicare CLFS from the first data reporting period is available on the CLFS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf*.

Given that section 1834A(a)(8)(B) of the Act specifically defines MA plans under Part C as private payors, and an applicable laboratory that receives MA plan payments must consider those MA plan payments in identifying its applicable information for reporting, we believe that it is more logical to consider MA plan payments only as private payor rates for purposes of reporting applicable information, rather than both private payor rates and Medicare revenues. We believe this is consistent with the statute and will help to increase laboratory participation from all types of laboratories. At the same time, we recognize the administrative concerns raised by some commenters regarding the data reporting requirements for laboratories with a significant Medicare Part C revenue component, particularly as some of these laboratories may be small physician offices or independent laboratories, which we have previously discussed as having a significant burden in reporting applicable information. However, as discussed previously in response to comments, we believe that modifying our definition of applicable laboratory so that we may receive applicable information from more laboratories that furnish tests to a significant Medicare Part C population, which are less likely to qualify for applicable laboratory status under the current policy, outweighs the additional reporting burden placed on these laboratories as well as directly supports our goal of collecting as much applicable information as possible from the broadest representation of the national laboratory market on which to base CLFS payment amounts. For these reasons we are finalizing our proposal to modify the definition of applicable laboratory to exclude MA plan revenues from total Medicare revenues (the denominator of the majority of Medicare revenues threshold). We are revising paragraph (3) of the definition of applicable laboratory at § 414.502 accordingly.

Comment: In addition to CMS' proposal to exclude MA plan payments from total Medicare revenues, one commenter recommended that CMS also remove prescription drug payments under Medicare Part D from the description of total Medicare revenues in the applicable laboratory definition. The commenter stated that including Part D payments is illogical because there is no circumstance under which such payments would be related to laboratory testing.

Response: As discussed previously, we are finalizing our proposal to modify the definition of applicable laboratory to exclude MA plan payments from total Medicare revenues, the denominator of the majority of Medicare revenues threshold, so that more types of laboratories may qualify as an applicable laboratory. While the agency did not propose or solicit comments on the possibility of excluding Medicare Part D revenues from total Medicare revenues, we will take the commenter's suggestion into consideration for future refinements to the CLFS. However, we note that if the commenter is correct that there is no circumstance under which such payments would be related to laboratory testing, then whether Part D payments are included or excluded from the denominator would have no effect on the calculation.

4. Solicitation of Public Comments on Other Approaches To Defining Applicable Laboratory

As discussed in the CY 2019 PFS proposed rule (83 FR 35858), and as noted previously, we define applicable laboratory at the NPI level, which means the laboratory's own billing NPI is used to identify a laboratory's revenues for purposes of determining whether it meets the majority of Medicare revenues threshold and the low expenditure threshold components of the applicable laboratory definition. For background purposes, the following summarizes some of the considerations we made in establishing this policy.

In the CLFS proposed rule, entitled Medicare Clinical Diagnostic Laboratory Tests Payment System, published in the October 1, 2015 **Federal Register**, we proposed to define applicable laboratory at the TIN level so that an applicable laboratory would be an entity that reports tax-related information to the IRS under a TIN with which all of the NPIs in the entity are associated, and was itself a laboratory or had at least one component that was a laboratory, as defined in § 493.2. In the CLFS proposed rule, we discussed that we considered proposing to define applicable laboratory at the NPI level. However, we did not propose that approach because we believed private payor rates for CDLTs are negotiated at the TIN level and not by individual laboratory locations at the NPI level. Numerous stakeholders had indicated that the TIN-level entity is the entity negotiating pricing, and therefore, is the entity in the best position to compile and report applicable information across its multiple NPIs when there are multiple NPIs associated with a TIN-level entity. We stated that we believed defining applicable laboratory by TIN rather than NPI would result in the same applicable information being reported, and would require reporting by fewer entities, and therefore, would be less burdensome to applicable laboratories. In addition, we stated that we did not believe reporting at the TIN level would affect or diminish the quality of the applicable information reported. To the extent the information is accurately reported, we expected reporting at a higher organizational level to produce exactly the same applicable information as reporting at a lower level (80 FR 59391 through 59393).

Commenters who objected to our proposal to define applicable laboratory at the TIN level stated that our definition would exclude hospital laboratories because, in calculating the applicable laboratory's majority of Medicare revenues amount, which looks at the percentage of Medicare revenues from the PFS and CLFS across the entire TIN-level entity, virtually all hospital laboratories would not be considered an applicable laboratory. Many commenters expressed particular concern that our proposed definition would exclude hospital outreach laboratories, stating that hospital outreach laboratories, which do not provide laboratory services to hospital patients, are direct competitors of the broader independent laboratory market, and therefore, excluding them from the definition of applicable laboratory would result in incomplete and inappropriate applicable information, which would skew CLFS payment rates. Commenters maintained that CMS needed to ensure reporting by a broad scope of the laboratory market to meet what they viewed as the intent of the statute that all sectors of the laboratory market be included to establish accurate market-based rates (81 FR 41045).

In issuing the CLFS final rule, we found particularly compelling the comments that urged us to adopt a policy that would better enable hospital outreach laboratories to be applicable laboratories because we agreed hospital outreach laboratories should be included in determining the new CLFS payment rates. We believed it was important to facilitate reporting of private payor rates for hospital outreach laboratories to ensure a broader representation of the national laboratory

market to use in setting CLFS payment amounts (81 FR 41045).

We also stated in the CLFS final rule that we believed the intent of the statute was to effectively exclude hospital laboratories as applicable laboratories, based on the statutory language, in particular, regarding the majority of Medicare revenues threshold criterion in section 1834A(a)(2) of the Act. Section 1834A(a)(2) of the Act provides that, to qualify as an applicable laboratory, an entity's revenues from the CLFS and the PFS need to constitute a majority of its total Medicare payments received from the Medicare program for a data collection period. What we found significant was that most hospital laboratories would not meet that majority of Medicare revenues threshold because their revenues under the Inpatient Prospective Payment System (IPPS) and Outpatient Prospective Payment System (OPPS) alone would likely far exceed the revenues they received under the CLFS and PFS. Therefore, we stated that we believe the statute intended to limit reporting primarily to independent laboratories and physician offices (81 FR 41045 through 41047). For a full discussion of the definition of applicable laboratory, see the CLFS final rule (81 FR 41041 through 41051).

a. Stakeholder Continuing Comments and Stakeholder-Suggested Alternative Approaches

As noted above, in response to public comments, we had previously finalized that an applicable laboratory is the NPI-level entity so that a hospital outreach laboratory assigned a unique NPI, separate from the hospital of which it is a part, is able to meet the definition of applicable laboratory and its applicable information can be used for CLFS rate-setting. We stated in the CY 2019 PFS proposed rule that we continue to believe that the NPI is the most effective mechanism for identifying Medicare revenues for purposes of determining applicable laboratory status and identifying private payor rates for purposes of reporting applicable information. Once a hospital outreach laboratory obtains its own unique billing NPI and bills for services using its own unique NPI, Medicare and private payor revenues are directly attributable to the hospital outreach laboratory. By defining applicable laboratory using the NPI, Medicare payments (for purposes of determining applicable laboratory status) and private payor rates and the associated volume of CDLTs can be more easily identified and reported to us. We also noted that we believe that finalizing our proposal to exclude MA plan payments under Medicare Part C from total Medicare revenues in the definition of applicable laboratory may increase the number of entities meeting the majority of Medicare revenues threshold, and therefore, allow them to qualify for applicable laboratory status. We stated that we believe that finalizing the change to the total Medicare revenues component of the applicable laboratory definition and our current policy that requires an entity to bill Medicare Part B under its own NPI, may increase the number of hospital outreach laboratories qualifying as applicable laboratories.

In addition, we noted that we are confident that our current policy supports our collecting sufficient applicable information in the next data reporting period, and that we received sufficient and reliable applicable information with which we set CY 2018 CLFS rates, and that those rates are accurate. We noted that we received applicable information from laboratories in every state, the District of Columbia, and Puerto Rico. This data included private payor rates for almost 248 million laboratory tests conducted by 1,942 applicable laboratories, with over 4 million records of applicable information. As we have noted, the largest laboratories dominate the market, and therefore, most significantly affect the payment weights (81 FR 41049). We stated that given that the largest laboratories reported their applicable information to CMS in the initial data reporting period, along with many smaller laboratories, we believe the data we used to calculate the CY 2018 CLFS rates was sufficient and resulted in accurate weighted medians of private payor rates.

However, we noted that we continue to consider refinements to our policies that could lead to including even more applicable information for the next data reporting period. Therefore, the comments and alternative approaches suggested by commenters, even though some were first raised prior to the CLFS final rule, were presented and offered for comment as part of the proposed rule.

(1) Using Form CMS–1450 UB 04 (and Electronic Equivalent, 837I) 14X Type of Bill (TOB) To Determine Majority of Medicare Revenues and Low Expenditure Thresholds

Although an NPI-based definition of applicable laboratories includes more hospital outreach laboratories than a TIN-based definition, some commenters expressed concern that the NPI-based definition of applicable laboratory may not be sufficient to capture all of the hospital outreach laboratories. These commenters suggested we revise the definition specifically for the purpose of including more hospital outreach laboratories. Under a suggested approach, a laboratory could determine whether it meets the majority of Medicare revenues threshold and low expenditure threshold using only the revenues from services reported on the Form CMS–1450 (approved Office of Management and Budget number 0938–0997) 14x Type of Bill (TOB), which is used only by hospital outreach laboratories. The CMS–1450 14X TOB is the uniform bill (also known as the UB–04) for institutional providers that was approved by the National Uniform Billing Committee (NUBC)[8] at its February 2005 meeting.

The data elements referenced in the UB–04 manual are also used in the electronic claim standard as required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191, enacted August 21, 1996) as per of sections 1171 and 1172 of the Act. Consequently, there was additional emphasis placed on aligning the reporting instructions to closely mirror the HIPAA claim standard for institutional providers for both paper and electronic claims. The TOB is a required element on both the UB 04 and electronic equivalent of the 837I transaction of the HIPAA compliant 005010 standard transaction. The NUBC defines the 14X TOB as an outpatient hospital TOB, and it is used by hospitals to bill a payor for outreach laboratory services for non-patients. As discussed in Transmittal 3425, a non-patient is defined as a beneficiary who is neither an inpatient nor an outpatient of a hospital, but who has a specimen that is submitted for analysis to a hospital and the beneficiary is not physically present at the hospital for purposes of the laboratory service. All hospitals (including Critical Access Hospitals) bill non-patient laboratory tests on a TOB 14X. They are paid under the CLFS, and the Part B deductible and coinsurance do not apply. We believe that laboratory services billed on the CMS 1450 14X encompass all of the laboratory testing services.

To address this stakeholder's concern of including hospital outreach laboratories, we solicited public comments in the CY 2019 PFS on revising the definition of applicable laboratory to permit the revenues identified on the Form CMS–1450 14x

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TOB to be used instead of the revenues associated with the NPI that the laboratory uses in order to determine whether it meets the majority of Medicare revenues threshold (and the low expenditure threshold). Under this approach, the applicable revenues would be based on the bills used for hospital laboratory services provided to non-patients, which are paid under Medicare Part B (that is, the 14x TOB). If we pursued this approach, we explained that we would have to modify the definition of applicable laboratory in § 414.502 by indicating that an applicable laboratory may include an entity that bills Medicare Part B on the Form CMS–1450 14x TOB.

Although using the 14x TOB could alleviate some initial, albeit limited, administrative burden on hospital outreach laboratories to obtain a unique billing NPI, we explained that we would have operational and statutory authority concerns about defining applicable laboratory by the Form CMS–1450 14x TOB, as indicated below.

First, we explained that defining an applicable laboratory using the Form CMS–1450 14x TOB does not identify an entity the same way an NPI does. Whereas an NPI is associated with a provider or supplier to determine specific Medicare revenues, the 14x TOB is merely a billing mechanism that is currently used only for a limited set of services. Under an approach that permits laboratories to meet the majority of Medicare revenues threshold using the 14x TOB, private payor rates (and the volume of tests paid at those rates) would have to be identified that are associated with only the outreach laboratory services of a hospital's laboratory business. However, some private payors, such as MA plans, may not require hospital outreach laboratories to use the 14x TOB for their outreach laboratory services. To the extent a private payor does not require hospital outreach laboratory services to be billed on a 14x TOB (which specifically identifies outreach services), hospitals may need to develop their own mechanism for identifying and reporting only the applicable information associated with its hospital outreach laboratory services. In light of this possible scenario, we requested public comments about the utility of using the 14x TOB in the way we have described and on the level of administrative burden created if we defined applicable laboratory using the Form CMS–1450 14x TOB.

Second, we questioned whether hospitals would have sufficient time after publication of a new final rule that included using the Form CMS–1450 14x TOB, and any related subregulatory guidance, to develop and implement the information systems necessary to collect private payor rate data before the start of the next data collection period, that is, January 1, 2019. Therefore, we solicited public comments as to whether revising the definition of applicable laboratory to use the Form CMS–1450 14x TOB would allow laboratories sufficient time to make the necessary systems changes to identify applicable information before the start of the next data collection period.

Third, we noted that we believe defining applicable laboratory at the NPI level, as we currently do, provides flexibility for hospital outreach laboratories to not obtain a unique billing NPI, which may be burdensome, particularly where a hospital outreach laboratory performs relatively few outreach services under Medicare Part B. For example, under the current definition of applicable laboratory, if a hospital outreach laboratory's CLFS revenues in a data collection period are typically less than the low expenditure threshold, the hospital of which it is a part could choose not to obtain a separate NPI for its outreach laboratory and could thus avoid determining applicable laboratory status for its outreach laboratory component. In contrast, if laboratories were permitted to use the Form CMS–1450 14x TOB, revenues attributed to the hospital outreach laboratory would have to be calculated in every instance where those services exceeded the low expenditure threshold. This would be true even for a hospital outreach laboratory that performs relatively few outreach services under Medicare Part B. Therefore, we also solicited comments concerning this aspect of using the 14x TOB definition.

Fourth, and significantly, we stated that we believe that if we were to utilize such an approach in defining applicable laboratory, all hospital outreach laboratories would meet the majority of Medicare revenues threshold. We noted, at that time, we believed this approach would be inconsistent with the statute. By virtue of the majority of Medicare revenues threshold, the statute defines applicable laboratory in such a way that not all laboratories qualify as applicable laboratories. However, if we were to use the CMS–1450 14x TOB to define an applicable laboratory, all hospital outreach laboratories that use the 14x TOB would meet the majority of Medicare revenues threshold. Accordingly, we requested public comments regarding whether this definition would indeed be inconsistent with the statute, as well as comments that could identify circumstances under this definition whereby a hospital outreach laboratory would not meet the majority of Medicare revenues threshold.

The following is a summary of the comments we received and our responses to the comments regarding the use of the CMS–1450 14x TOB to define an applicable laboratory.

Comment: We received conflicting comments on this potential refinement to the definition of an applicable laboratory. Some commenters supported using the CMS–1450 14x TOB as a mechanism to define an applicable laboratory, and others were opposed to this approach. The commenters who supported this believe that it provides an opportunity for hospital outreach laboratories that have not obtained an NPI separate from the hospital to qualify as an applicable laboratory and report applicable information. These commenters opined that since the 14X TOB is used only to submit claims by hospital outreach laboratories for non-patient claims, this approach would include hospital laboratories without their own NPI who compete in the marketplace with independent clinical laboratories. These commenters also noted that, in their view, this approach would effectuate Congress' intent to determine whether a majority of Medicare revenues attributable to the laboratory part of the hospital—as opposed to the entire hospital—was from the CLFS and/or PFS.

Another commenter stated their view that considerable burden is associated with requiring a hospital outreach laboratory to obtain its own NPI. According to this commenter, a hospital would need to re-credential under a new NPI with each of their payors in order to submit claims and receive payment from each of their payors for their hospital outreach laboratory services. This commenter stated that this process could take more than a year to complete. Accordingly, this commenter concluded that hospital outreach laboratories rarely obtain their own unique NPI (separate from the hospital) and it would not be practical to do so for the single purpose of reporting applicable information to CMS.

Additional commenters in support of refinements to the definition responded to CMS' concern that revenues attributed to the hospital outreach laboratory would have to be calculated in every instance where those services exceeded the low expenditure threshold, even for a hospital outreach laboratory that performs relatively few outreach services under Medicare Part

B. In response to this concern, commenters noted that this refinement to the definition would require hospital outreach laboratories to have the same obligations as other laboratories that exceed the low expenditure threshold and that serve non-hospital patients. Furthermore, commenters suggested that if CMS is concerned that refinements to the definition would result in all hospital outreach laboratories meeting the majority of Medicare revenues threshold, that is the case for almost all independent laboratories, as well, where hospital outreach laboratories compete with independent laboratories in the marketplace. Furthermore, they stated it is reasonable that a laboratory whose revenues are derived primarily from the CLFS and/or PFS and that meets the low expenditure threshold be included in data reporting, regardless if it is a hospital outreach laboratory.

In contrast, several commenters strongly opposed the use of Form CMS–1450 14x TOB to define an applicable laboratory because of their views of the additional administrative burden for hospitals relative to the effect on CLFS rates. These commenters stated that even if every hospital outreach laboratory were to report private payor data, it is unlikely that it would result in a significant change to the weighted median of private payor rates due to the massive amount of data that would be reported by the large independent laboratories. They also agreed with the potential operational feasibility concerns we raised in the proposed rule.

Response: We appreciate the comments raised about the administrative aspects of obtaining an NPI for a hospital outreach laboratory for the sole purpose of reporting data to CMS and the associated administrative burden. We agree that one advantage of using the Form CMS–1450 14x TOB to define an applicable laboratory is that it provides an opportunity for more hospital outreach laboratories to report data for calculating CLFS rates. However, we also recognize that this will result in additional administrative burden on the hospital industry, such as changes to collect and report applicable information. We discuss specific operational concerns in more detail in the sections below. However, we generally believe that this advantage outweighs the potential burden for hospital outreach laboratories, the data collected from hospital outreach laboratories will create a dataset that is a more robust representation of the laboratory testing market, and that this outweighs the potential burden to hospital outreach laboratories. Accordingly, we are finalizing the use of the Form CMS–1450 14x TOB to define applicable laboratories for the next data collection period (January 1, 2019, through June 30, 2019) and the next data reporting period (January 1, 2020, and ends March 31, 2020), subject to other regulatory and subregulatory requirements, such as the regulatory low expenditure threshold.

We also considered the comments regarding the limited impact of this additional data to the weighted median of private payor rates. We believe that we will only know the impact of the data on CLFS rates by collecting data from hospital outreach laboratories. We believe inclusion of this information so that the CLFS rates better reflect the market outweighs the potential added burden on one segment of the market. However, if it becomes apparent that data from hospital outreach laboratories do not result in a significant change in the weighted median of private payor rates, we will revisit the use of the CMS–1450 14x TOB through future rulemaking.

Comment: A few commenters stated that CMS should not be concerned that hospitals will need to develop additional mechanisms to identify applicable information if private payors do not require hospital outreach laboratories to use the CMS–1450 14x TOB. They noted that this point is not relevant to reporting private payor rates because once applicable laboratory status is determined, the hospital outreach laboratory ''can simply report its private payor data for all of its fee for service work that is not part of a capitated plan.'' The commenters stated that the reporting entities for all other laboratory types would have the same burden as hospital outreach laboratories, that is, of identifying and reporting accurate applicable information.

In contrast, several stakeholders raised concerns about the implications this alternative approach would have on identifying applicable information for purposes of reporting that data to us. They stated that the Form CMS–1450 14x TOB will only capture Medicare Part B revenues, while private payor data would not be captured. In other words, the 14x TOB will correctly identify Medicare Part B revenues for purposes of determining applicable laboratory status, but that the hospital would be responsible for correctly identifying and collecting applicable information associated solely with the hospital outreach laboratory. Several commenters stated that billing systems for hospital outreach laboratories are not set up in a manner that allows this type of information to be easily extracted, and therefore, this approach to defining an applicable laboratory would pose a significant operational burden on hospitals.

Response: We note that hospital outreach laboratories who meet the definition of an applicable laboratory would have the same burden of identifying and reporting accurate applicable information as all other laboratory types that meet the definition of an applicable laboratory.

Comment: Some commenters stated that they believe hospitals would have sufficient time to develop and implement the information systems necessary to collect private payor rate data before the start of the next data collection period, and noted that even though the CLFS final rule was published less than 2 weeks prior to the end of the first data collection period, applicable laboratories were able to develop and implement the information systems necessary to collect private payor rate data and report it to CMS. However, several commenters expressed serious concerns about developing the systems to collect applicable information before the next data reporting period. They indicated that finalizing this alternative approach for defining an applicable laboratory would not allow hospital outreach laboratories sufficient time to make the necessary systems changes prior to the start of the next data collection, and as a result, there would be a risk that inaccurate data would be reported.

Response: As discussed previously in this section, the next data collection period is January 1, 2019, through June 30, 2019. A 6-month window follows the data collection period from July 1, 2019, through December 31, 2019 and the next data reporting period begins January 1, 2020, and ends March 31, 2020. While several commenters raised concerns about the operational changes needed for reporting before the next data collection period, we believe that, similar to the retroactive data collection that occurred under the initial private payor rate-based CLFS, hospitals, including the part of the hospital represented by their hospital outreach laboratories, could develop these operational changes in time. For example, hospitals, including the part of the hospital represented by their hospital outreach laboratories, could use the time before and during the next data collection period to develop processes to collect applicable information, the 6-month window between the collection and reporting periods to determine applicable laboratory status and retroactively collect applicable

information to report it before the close of the next data reporting period (March 31, 2020).

Comment: Many commenters noted the concern that hospital outreach laboratories would lose the flexibility to not obtain an NPI for low volume hospital outreach laboratories. For instance, they stated all hospitals would be required to go through the exercise of determining applicable laboratory status for their hospital outreach laboratory components. However, a few commenters indicated that hospital outreach laboratories would have the same obligations as every other laboratory to determine whether it is an applicable laboratory. Therefore, in their view, the loss of flexibility for hospital outreach laboratories to not obtain an NPI should not be a concern.

Response: We agree that the use of Form CMS–1450 14x TOB to define an applicable laboratory will require hospitals to assess applicable laboratory status for all outreach laboratory components, similar to the obligations of other laboratory types. For instance, all independent and physician office laboratories billing Medicare Part B under their own NPI must assess whether they qualify as an applicable laboratory, and if so, report applicable information to us. Consequently, independent and physician office laboratories do not have the flexibility of not reporting private payor data that is currently afforded to hospital outpatient laboratories. Use of the 14x TOB to define an applicable laboratory would equalize the obligations across laboratories, regardless of their affiliation with a hospital, to determine whether they qualify for applicable laboratory status. We note that, insofar as commenters expressed concern about low volume hospital outreach laboratories, our policy regarding laboratories receiving less than a minimum in CLFS revenues remains unchanged. Specifically, hospital outreach laboratories that do not receive at least $12,500 in CLFS revenues on the 14X TOB during a data collection period would be exempt from the reporting requirements.

Comment: Several commenters noted that by using the 14x TOB to define an applicable laboratory, all hospital outreach laboratories would meet the majority of Medicare revenues threshold. They, therefore, raised concerns about the legality of this approach. For instance, some commenters stated their view that Congress did not intend for all hospital outreach laboratories to qualify as applicable laboratories. In contrast, some commenters stated their view that Congress clearly intended for the CLFS to reflect a market-based system that includes hospital outreach laboratories and that it is reasonable for a laboratory with revenues derived primarily from the CLFS and/or PFS that also meets the low expenditure threshold to be an applicable laboratory, regardless of whether it is a hospital outreach laboratory or not.

Response: After further review of this issue, we believe that using Form CMS–1450 14x TOB provides a means of distinguishing services furnished by a hospital outreach laboratory from other services furnished and billed by a hospital using the same NPI. The statute specifically directs us to identify applicable ''laboratories'' and not ''providers'' or ''suppliers.'' We believe that hospital outreach laboratories without unique NPIs furnish clinical laboratory tests paid under the CLFS and PFS, albeit to Medicare beneficiaries who are not hospital patients. Accordingly, we believe such laboratories, should not be exempt from reporting the applicable data merely due to their shared use of a billing entity with a hospital.

Using the laboratory's own billing NPI as the basis for defining applicable laboratory, as we currently do, results in all independent laboratories meeting the statutory ''majority of Medicare revenues'' requirement because most, if not all, of an independent laboratory's Medicare revenues are received from the PFS and or CLFS. Similar to how the use of the NPI results in all independent laboratories meeting the majority of Medicare revenues threshold, using the Form CMS–1450 14x TOB as the basis for defining applicable laboratory would identify all hospital outreach laboratories that meet the statutorily required ''majority of Medicare revenues'' component of applicable laboratory.

We believe that the use of Form CMS–1450 14x TOB as a mechanism for applying the majority of Medicare revenues threshold identifies hospital outreach laboratories that meet this threshold, consistent with the statutory requirement for applicable laboratory status. We further believe that, absent having an NPI separate from the hospital, these hospital outreach laboratories otherwise would be excluded. We do not believe that the statute excludes laboratories that meet the majority of Medicare revenues threshold from potentially qualifying as an applicable laboratory. Therefore, using the 14x TOB to define applicable laboratory is consistent with the statute.

As stated above, accordingly, we are finalizing the use of the Form CMS–1450 14x TOB to define applicable laboratories, subject to other regulatory and subregulatory requirements, such as the regulatory low expenditure threshold.

Comment: Two commenters stated that it is unclear whether the burden associated with considering every hospital outreach laboratory to meet the majority of Medicare revenues threshold and an applicable laboratory (if the low expenditure threshold is also met) would outweigh the additional applicable information that would be reported. Therefore, they requested that we continue evaluating this approach before implementing any changes.

Response: As we stated previously, we generally believe that the advantage of including private payor data from hospital outreach laboratories in setting CLFS rates outweighs the potential burden for hospital outreach laboratories; data collected from hospital outreach laboratories will create a dataset that is a more robust representation of the laboratory testing market. We also note that the timing of the data collection and reporting periods, and the 6 month window in between provide time for laboratories to implement needed operational changes.

Comment: One commenter suggested that an alternative approach to identifying applicable laboratories would be for the hospital to develop an ''adjustment factor'' based on its payment-to-charges ratio to estimate laboratory revenues received from the IPPS and OPPS. The same commenter suggested that we remove the requirement that an applicable laboratory is an entity that bills Medicare Part B under its own NPI and that we amend the majority of Medicare revenues threshold so that ''Medicare revenues'' means payment for claims submitted on a CMS 1500, a CMS 1450 using a 14x TOB, or their electronic equivalents.

Response: We appreciate this suggested approach and we may consider it in future rulemaking.

In conclusion, as stated previously and for the reasons described previously, we are finalizing the use of the Form CMS–1450 14x TOB to define applicable laboratories, subject to other regulatory and subregulatory requirements, such as the regulatory low expenditure threshold.

We note that because of the low expenditure threshold, not all hospital outreach laboratories would meet the definition of an applicable laboratory and therefore not all hospital outreach laboratories would be required to report applicable information to us. In other words, hospital outreach laboratories

that do not receive at least $12,500 in CLFS revenues on the 14X TOB during a data collection period would be exempt from the reporting requirements.

We believe that defining applicable laboratory by the NPI may be preferable to using the CMS–1450 14x TOB for some hospitals and so expect that some hospital outreach laboratories may still want to obtain their own billing NPI separate from the hospital. As such, they may do so and may qualify as an applicable laboratory in this manner. If so, they would report applicable information during the next data reporting period beginning January 1, 2020, through March 31, 2020.

We note that we utilize ongoing subregulatory guidance and provider education materials to provide more details regarding how applicable laboratories, both those identified through NPIs and hospital outreach laboratories identified through the combination of NPI and services reported using the 14x TOBs, are to report the applicable data to CMS. We also note that for hospitals which have an applicable laboratory, whether via its own NPI for its outreach laboratory or by identifying its status with the 14X TOB, the applicable laboratory would be required to report applicable information by March 31, 2020, for services reimbursed for the period between January 1, 2019, and June 30, 2019.

In conclusion, as stated previously, we are finalizing the use of the Form CMS–1450 14x TOB to define applicable laboratories. In other words, we are finalizing modification of the definition of applicable laboratory to also include 14X TOB revenues. We will also revise paragraph (2) of the definition of applicable laboratory at § 414.502 accordingly.

(2) Using CLIA Certificate To Define Applicable Laboratories

Some commenters requested that we use the CLIA certificate rather than the NPI to identify a laboratory that would be considered an applicable laboratory. We discussed in the CLFS proposed rule (80 FR 59392) why not all entities that meet the CLIA regulatory definition at § 493.2 would be applicable laboratories, and therefore, we did not propose to use the CLIA certificate as the mechanism for defining applicable laboratory. However, some commenters to the CLFS proposed rule suggested we use the CLIA certificate to identify the organizational entity that would be considered an applicable laboratory so that each entity that had a CLIA certificate would be an applicable laboratory (81 FR 41045). We considered those comments in the CLFS final rule and discussed why we chose not to adopt that approach.

Among other reasons, we explained in the CLFS final rule that we believed a CLIA certificate-based definition of applicable laboratory would be overly inclusive by including all hospital laboratories, as opposed to just hospital outreach laboratories. In addition, the CLIA certificate is used to certify that a laboratory meets applicable health and safety regulations in order to furnish laboratory services. Unlike, for example, the NPI, with which revenues for specific services can easily be identified, the CLIA certificate is not associated with Medicare billing and cannot be used to identify revenues for specific services. We also indicated that we did not know how a hospital would determine whether its laboratories would meet the majority of Medicare revenues threshold (and the low expenditure threshold) using the CLIA certificate as the basis for defining an applicable laboratory. In addition, we stated that, given the difficulties many hospitals would likely have in determining whether their laboratories are applicable laboratories, we also believed hospitals may object to using the CLIA certificate (81 FR 41045).

However, in light of stakeholders' suggestions to use the CLIA certificate to include hospital outreach laboratories in the definition of applicable laboratories, we solicited public comments on that approach. Under such an approach, the majority of Medicare revenues threshold and low expenditure threshold components of the definition of applicable laboratory would be determined at the CLIA certificate level instead of the NPI level. We explained that if we pursued such an approach, we would have to modify the definition of applicable laboratory in § 414.502 to indicate that an applicable laboratory is one that holds a CLIA certificate under § 493.2 of the chapter. We noted in the CY 2019 PFS proposed rule that we would have concerns, however, about defining applicable laboratory by the CLIA certificate.

First, we explained that as we discussed in the CLFS final rule, given that information regarding the CLIA certificate is not required on the Form CMS–1450 14x TOB, which is the billing form used by hospitals for their laboratory outreach services, it is not clear how a hospital would identify and distinguish revenues generated by its separately CLIA-certified laboratories for their outreach services. Therefore, we solicited public comments regarding the mechanisms a hospital would need to develop to identify revenues if we used the CLIA certificate for purposes of determining applicable laboratory status, as well as comments about the administrative burden associated with developing such mechanisms.

In addition, we understood there could be a scenario where one CLIA certificate is assigned to a hospital's entire laboratory business, which would include laboratory tests performed for hospital patients as well as non-patients (that is, patients who are not admitted inpatients or registered outpatients of the hospital). For example, hospital laboratories with an outreach laboratory component would be assigned a single CLIA certificate if the hospital outreach laboratory has the same mailing address or location as the hospital laboratory. We noted that in this scenario, the majority of Medicare revenues threshold would be applied to the entire hospital laboratory, not just its outreach laboratory component. If a single CLIA certificate is assigned to the hospital's entire laboratory business, the hospital laboratory would be unlikely to meet the majority of Medicare revenues threshold because its laboratory revenues under the IPPS and OPPS alone would likely far exceed the revenues it receives under the CLFS and PFS. As a result, a hospital outreach laboratory that could otherwise meet the definition of applicable laboratory, as currently defined at the NPI level, would not be an applicable laboratory if we were to require the CLIA certificate to define applicable laboratory. Given that this approach could have the effect of decreasing as opposed to increasing the number of applicable laboratories, we requested public comments on this potential drawback of defining applicable laboratory at the CLIA certificate level. We stated in the comment solicitation that feedback on this topic could help inform us regarding potential refinements to the definition of applicable laboratory, and that depending on the comments we receive, it is possible we would consider approaches described in that section. The following is a summary of the comments we received and our responses to the comments regarding the use of the CLIA certificate to define an applicable laboratory.

Comment: Many commenters did not support using the CLIA certificate to define applicable laboratory because of the administrative complexity associated with this approach. Commenters stated that the CLIA certificate has no relationship to actual laboratory revenues, like the NPI does, and therefore, laboratories would need to develop their own mechanisms to attribute Medicare revenues to the CLIA

certificate. Commenters stated that any ''workaround'' to resolve these issues would be extremely burdensome to develop and implement. These same commenters also noted that when one CLIA certificate is assigned to a hospital's entire laboratory business, which would include laboratory tests performed for hospital patients as well as non-patients, the total Medicare revenues component of the majority of Medicare revenues threshold equation would be ''overly inclusive.'' Therefore, they agreed with CMS' concern that hospital outreach laboratories would be unlikely to meet the majority of Medicare revenues threshold under those circumstances because revenues from the IPPS and OPPS alone would likely far exceed the revenues those laboratories receive under the CLFS and PFS. For these reasons, they encouraged CMS to reject the use of the CLIA certificate for defining an applicable laboratory.

Response: We agree that defining applicable laboratory by the CLIA certificate would result in substantial administrative burden for the laboratory industry. From an administrative perspective, we believe the using the CLIA certificate unworkable for the purpose of determining applicable laboratory status because the CLIA certificate is not required on the CMS 1450 14x TOB which is the billing form used by hospital outreach laboratories. Therefore, no revenues can be readily identified by the CLIA certificate. Even if the hospital developed its own mechanism to identify revenues by the CLIA certificate, the CLIA certificate could be assigned to the hospital's entire laboratory business, which includes laboratory tests performed for hospital patients, as well as non-patients. For example, we understand hospital-based laboratories with an outreach component would be assigned a single CLIA certificate if the hospital outreach laboratory has the same mailing address or location as the main laboratory. In this scenario, the applicable laboratory criteria would be applied to the CLIA certificate of the entire hospital laboratory not just its outreach laboratory component. When a single CLIA certificate is assigned to the hospital's entire laboratory business, we believe it would result in the hospital laboratory not meeting the majority of Medicare revenues threshold because its laboratory revenues under the IPPS and OPPS alone will far exceed the revenues it receives under the CLFS and PFS. We also understand that a hospital could have multiple outreach laboratories each with its own CLIA certificate. Therefore, we believe those hospitals would also have difficulties separating Medicare revenues and applicable information among their various CLIA certificates as described below.

Comment: One commenter stated that it is unlikely that a single CLIA certificate would be assigned to both its outreach laboratory (non-patients) and its laboratory that that provides testing for its hospital inpatients and hospital outpatients. The commenter stated that it would be more likely that the outreach laboratory would be at a different location than the hospital and therefore, be assigned its own CLIA certificate even though the outreach laboratory is enrolled in the Medicare program under the hospital's NPI. As such, the commenter stated that an outreach laboratory operates as a distinct laboratory entity by virtue of having its own CLIA certificate and billing on the Form CMS–1450 14x TOB. The commenter suggested that the 14x TOB could be used in combination with each individual CLIA certificate to define applicable laboratory.

Response: We understand that the assignment of CLIA certificates for hospital outreach laboratories could vary depending on the location of the outreach laboratory. As discussed previously, Medicare revenues are not attributed to the CLIA certificate and information regarding the CLIA certificate is not required on the Form CMS–1450 14x TOB. As such, we believe the commenter's suggestion would result in defining applicable laboratory by the Form CMS–1450 14x TOB. We note that in cases in which a hospital owns and operates multiple outreach laboratories at different locations, we believe the administrative burden of attributing Medicare revenues to the CLIA certificate would be even more substantial as there could be several CLIA certificates assigned under the same NPI. In such cases, the hospital would need to attribute laboratory revenues among multiple CLIA certificates under the same billing entity. In other words, if the 14x TOB is used by a hospital to bill for laboratory tests furnished by more than one CLIA certificate under the same NPI, the hospital would need to devise a mechanism to attribute Medicare revenues to each individual CLIA certificate.

5. Solicitation of Public Comments on the Low Expenditure Threshold in the Definition of Applicable Laboratory

a. Decreasing the Low Expenditure Threshold

In the CLFS final rule, we established a low expenditure threshold component in the definition of applicable laboratory at § 414.502, which is reflected in paragraph (4). To be an applicable laboratory, at least $12,500 of an entity's Medicare revenues in a data collection period must be CLFS revenues (with the exception that there is no low expenditure threshold for an entity with respect to the ADLTs it furnishes). We established $12,500 as the low expenditure threshold because we believed it achieved a balance between collecting sufficient data to calculate a weighted median that appropriately reflects the private market rate for a test, and minimizing the reporting burden for laboratories that receive a relatively small amount of revenues under the CLFS. We indicated in the CLFS final rule (81 FR 41049) that once we obtained applicable information under the new payment system, we may decide to reevaluate the low expenditure threshold in future years and propose a different threshold amount through notice and comment rulemaking.

We explained in the CY 2019 PFS proposed rule that we recently heard from some laboratory stakeholders that the low expenditure threshold excludes most physician office laboratories and many small independent laboratories from reporting applicable information, and that by excluding so many laboratories, the payment rates under the new private payor rate-based CLFS reflect incomplete data, and therefore, inaccurate CLFS pricing.

As noted previously, we discussed in the CLFS final rule that we believed a $12,500 low expenditure threshold would reduce the reporting burden on small laboratories. In the CLFS final rule (81 FR 41051), we estimated that 95 percent of physician office laboratories and 55 percent of independent laboratories would not be required to report applicable information under our low expenditure criterion. Although we substantially reduced the number of laboratories qualifying as applicable laboratories (that is, approximately 5 percent of physician office laboratories and approximately 45 percent of independent laboratories), we estimated that the percentage of Medicare utilization would remain high. That is, approximately 5 percent of physician office laboratories would account for approximately 92 percent of CLFS

spending on physician office laboratories and approximately 45 percent of independent laboratories would account for approximately 99 percent of CLFS spending on independent laboratories (81 FR 41051).

We stated that it is our understanding that physician offices are generally not prepared to identify, collect, and report each unique private payor rate from each private payor for each laboratory test code subject to the data collection and reporting requirements, and the volume associated with each unique private payor rate. As such, we explained that we believe revising the low expenditure threshold so that more physician office laboratories are required to report applicable information would likely impose significant administrative burdens on physician offices. We stated that we also believe that increasing participation from physician office laboratories would have minimal overall impact on payment rates given that the weighted median of private payor rates is dominated by the laboratories with the largest test volume. We noted that our participation simulations from the first data reporting period show that increasing the volume of physician office laboratories reporting applicable information has minimal overall impact on the weighted median of private payor rates. For more information on our participation simulations, please visit the CLFS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf*.

We stated in the proposed rule that we continue to believe the current low expenditure threshold strikes an appropriate balance between collecting enough private payor rate data to accurately represent the weighted median of private payor rates while limiting the administrative burden on small laboratories. In addition, as discussed previously in this section, we are finalizing excluding MA plan revenues under Part C from total Medicare revenues in the definition of applicable laboratory, and we noted that we expect more laboratories of all types, including physician office laboratories, may meet the majority of Medicare revenues threshold.

However, we recognized from stakeholders that some physician office laboratories and small independent laboratories that are not applicable laboratories because they do not meet the current low expenditure threshold may still want to report applicable information despite the administrative burden associated with qualifying as an applicable laboratory. Therefore, we sought public comment on revising the low expenditure threshold to increase the level of participation among physician office laboratories and small independent laboratories.

In the proposed rule we explained that one approach could be for us to decrease the low expenditure threshold by 50 percent, from $12,500 to $6,250, in CLFS revenues during a data collection period. Under such an approach, a laboratory would need to receive at least $6,250 in CLFS revenues in a data collection period. We stated that if we were to adopt such an approach, we would need to revise paragraph (4) of the definition of applicable laboratory at § 414.502 to replace $12,500 with $6,250. We solicited public comments on this approach.

We noted that we were particularly interested in comments from the physician community and small independent laboratories as to the administrative burden associated with such a revision to the low expenditure threshold. Specifically, we requested comments on the following issues: (1) Whether physician offices and small independent laboratories currently have adequate staff levels to meet the data collection and data reporting requirements; (2) whether data systems are currently in place to identify, collect, and report each unique private payor rate from each private payor for each CLFS test code and the volume of tests associated with each unique private payor rate; (3) if physician offices and small independent laboratories are generally not prepared to conduct the data collection and data reporting requirements, what is the anticipated timeframe needed for physician office and small independent laboratories to be able to meet the data collection and data reporting requirements; and (4) any other administrative concerns that decreasing the low expenditure threshold may impose on offices and small independent laboratories.

The following is a summary of the comments we received and our responses to the comments regarding the approach of decreasing the low expenditure threshold by 50 percent, from $12,500 to $6,250, in CLFS revenues during a data collection period.

Comment: Many commenters were opposed to reducing the low expenditure threshold because of the administrative burden it would place on physician office laboratories and small independent laboratories. Commenters noted that they experienced difficulties during the initial data collection and data reporting period with determining whether they met the definition of applicable laboratory and therefore if they were required to report applicable information. Some commenters that did report applicable information stated that they experienced significant administrative burden in collecting and compiling information, especially for test codes that involved numerous different sources of payment (such as the beneficiary's primary private payor, the beneficiary's secondary insurance, and coinsurance requirements). Some commenters reported having to remove staff from regular duties to work full time on preparing to report applicable information to CMS. A few commenters noted that physician office laboratories and small independent laboratories do not have the staffing or resources currently available, nor do they anticipate having them available in the future, to identify, collect and report each unique private payor rate for each CLFS test code and the volume of tests associated with each unique private payor rate. As such, commenters encouraged CMS not to decrease the low expenditure threshold component of the definition of applicable laboratory.

Response: We appreciate the comments regarding the administrative burden imposed by the data collection and reporting requirements on physician office laboratories and small independent laboratories and understand that reducing the low expenditure threshold by 50 percent would add more burden on this segment of the laboratory industry. We will consider the commenters' input regarding the low expenditure threshold as we continue to evaluate and refine Medicare CLFS payment policy in the future.

Comment: A few commenters suggested alternative approaches to lowering the low expenditure threshold that involve collecting data for physician office dependent tests and allowing laboratories to voluntarily report applicable information. For example, two commenters suggested that CMS identify laboratory tests predominantly performed by physician office laboratories and collect a statistically representative sample of data from physician office laboratories for the range of tests commonly performed in this setting. Under the commenters' approach, physician office laboratories would be required to report those tests. The commenters stated that this would ensure that the private payor rates for tests mostly performed by physician office laboratories are

represented in the weighted median of private payor rates used to determine CLFS rates. Moreover, a few other commenters suggested that CMS permit voluntary reporting so that laboratories that do not meet the current low expenditure threshold may report applicable information if they choose to.

Response: The suggestions to identify physician office laboratory dependent tests and to permit voluntary reporting have already been addressed in previous rulemaking and we chose not to adopt them (81 FR 41048). We noted that statute is clear about the particular information that is to be reported and on which we must base the new CLFS payment rates. Only applicable information of applicable laboratories is to be reported, and section 1834A(a)(3) of the Act indicates that applicable information is private payor rate information. We also explained that the statute imposes parameters on the collection and reporting of private payor rate information, and section 1834A(b) of the Act specifies that the payment amounts for CDLTs are to be based on the median of the private payor rate information. As such, we stated that we believe the statute supports our policy to prohibit information other than statutorily specified private payor rate information of applicable laboratories from being reported and used to set CLFS payment amounts under the revised CLFS. We also noted that we did not agree with the commenters' recommendation to allow voluntary reporting and at § 414.504(g), we finalized that an entity that does not meet the definition of an applicable laboratory may not report applicable information. We continue to believe that our policy to not allow voluntary reporting is the most appropriate interpretation of the statute, and that applicable information may not be reported for an entity that does not meet the definition of an applicable laboratory.

b. Increasing the Low Expenditure Threshold

We also discussed in the CY 2019 PFS proposed rule that we recognize many small laboratories may not want the additional administrative burden of data collection and reporting and, because their test volume is relatively low, their data is unlikely to have a meaningful impact on the weighted median of private payor rates for CDLTs under the CLFS. In response to comments from smaller laboratories that they prefer to not be applicable laboratories because of the burden of collecting and reporting applicable information, we stated that we could increase the low expenditure threshold in the definition of applicable laboratory by 50 percent, from $12,500 to $18,750, in CLFS revenues during a data collection period. Because physician office laboratories would be less likely to meet a higher threshold, such an approach would decrease the number of physician office laboratories and small independent laboratories required to collect and report applicable information. We noted that we expected decreasing the number of physician office laboratories and small independent laboratories reporting applicable information would have minimal impact on determining CLFS rates because the largest laboratories with the highest test volumes dominate the weighted median of private payor rates.

We stated that if we were to adopt such an approach, we would need to revise paragraph (4) of the definition of applicable laboratory at § 414.502 to replace $12,500 with $18,750. We explained in the proposed rule that we were particularly interested in comments from the physician community and small independent laboratories on the administrative burden and relief of increasing the low expenditure threshold and noted that we believe that feedback on the topics discussed in this section would help inform us regarding potential refinements to the low expenditure threshold. We noted that depending on the comments we received, we would consider approaches described in this section.

The following is a summary of the comments we received and our responses to the comments regarding the approach of increasing the low expenditure threshold by 50 percent, from $12,500 to $18,750, in CLFS revenues during a data collection period.

Comment: Several commenters did not support raising the low expenditure threshold because it would further reduce the amount of applicable information reported from small laboratories. However, one commenter encouraged CMS to increase the low expenditure threshold to exclude even more small laboratories from the administrative burden of collecting and reporting applicable information. A few commenters suggested that CMS not make any changes to the low expenditure threshold at this time and encouraged CMS to allow the program to mature and to only make changes after a careful and transparent review of the data with additional opportunities for public comment.

Response: We appreciate the comments from stakeholders on raising the low expenditure threshold and understand that increasing the low expenditure threshold by 50 percent would lead to fewer physician office laboratories and small independent laboratories from reporting applicable information for purposes of calculating CLFS rates. We will consider the commenters input on increasing the low expenditure threshold as we continue to evaluate and refine Medicare CLFS payment policy in the future, but make no changes to this policy at this time.

c. Additional Comments Received

Comment: Many commenters stated that CMS' implementation of the new private payor rate-based CLFS does not reflect the cost or the value of performing clinical laboratory services and that without meaningful changes to how data is collected from laboratories, Medicare beneficiaries will lose access to the vital laboratory services they rely on to monitor their health and prevent and treat many diseases and conditions. The commenters stated that CMS' regulations, which implemented the private payor rate-based CLFS required under PAMA, prohibit most independent laboratories and physician office laboratories, and virtually all hospital laboratories, from providing data to set Medicare rates, and therefore, results in ''skewed data'' that does not represent true market rates. The commenters stated that Congress directed CMS to implement a market-based payment system in which private market data from all segments of the laboratory industry, including independent laboratories, hospital laboratories, and physician office laboratories, would be collected in order to determine Medicare reimbursement for laboratory tests. To implement a true market based payment system the commenters encouraged CMS to develop payment rates through a statistically valid process to ensure that the private payer data collected accurately represents all sectors of the laboratory market.

Response: In general, section 1834A of the Act requires the payment amount for each CDLT on the CLFS to be based on the applicable information collected from applicable laboratories during a data collection period and reported to CMS during a data reporting period. For most tests on the CLFS, the statute requires the payment amount to be equal to the weighted median of the private payor rates for each test and specifies that the weighted median is calculated by arraying the distribution of all private payor rates, weighted by the volume for each payor and each laboratory. Given that the largest

laboratories reported their applicable information to CMS in the initial data reporting period, as well as many smaller laboratories, we believe the data we used to calculate the CY 2018 CLFS rates was sufficient and resulted in accurate weighted medians of private payor rates per test as required by the statute. As discussed previously in this section, we are finalizing our proposal to exclude MA plan payments under Part C from total Medicare revenues for purposes of the applicable laboratory definition. We believe this change will permit laboratories of all types with a significant Medicare Part C revenue component to be more likely to meet the majority of Medicare revenues threshold and qualify as an applicable laboratory. As a result of this change, we believe that applicable information from a broader segment of the laboratory industry will be reported for purposes of calculating the CLFS rates. As stated previously, we are finalizing the use of the Form CMS–1450 14x TOB to define applicable laboratories, subject to other regulatory and subregulatory requirements, such as the regulatory low expenditure threshold.

Comment: One commenter stated that the reductions in Medicare payment rates for laboratory tests result directly from CMS' regulatory decisions to relieve most laboratories of reporting burdens. According to the commenter, excluding so many laboratories from the data reporting requirements results in median prices that are not representative across the clinical laboratory industry. As such, the commenter noted that the market data upon which Medicare reimbursement is based does not reflect the market composition of the clinical laboratory industry. In other words, exempting low-volume and many hospital laboratories from reporting does not allow for Medicare prices to reflect the full range of payment amounts paid to varying entities. The commenter encouraged CMS to collect data from a broader segment of the laboratory industry and suggested that we weight private payor rates by market share (that is, prices typically paid per reporting entity), instead of based on overall volume per test.

Response: As discussed in response to the previous comment, section 1834A of the Act generally requires the payment amount for each CDLT on the CLFS to be based on the applicable information collected from applicable laboratories during a data collection period and reported to CMS during a data reporting period. Because for most tests, the payment amount is equal to the median of the private payor rates weighted by volume, the largest laboratories with the highest test volumes will most significantly affect the payment rates. Because of this, we established and implemented a low expenditure threshold to alleviate administrative burden on small laboratories. We believe that our current method of calculating the weighted median of private payor rates is appropriate and consistent with the statute. Given that the largest laboratories reported their applicable information to us in the initial data reporting period, along with many smaller laboratories, we believe the data we used to calculate the CY 2018 CLFS rates was sufficient and resulted in accurate weighted medians of private payor rates as required by statute. As noted above, we are finalizing changes to the definition of an applicable laboratory, which we believe will lead to an even more robust data collection from which to calculate payment rates for the next CLFS update.

Comment: Many commenters stated that the administrative burden for the first data reporting period was overwhelming and they offered suggestions on how to reduce the reporting burden on applicable laboratories. Many commenters suggested that CMS implement a ''data aggregation system'' consistent with statutory authority. In addition, a few commenters requested that CMS allow flexibility to exclude manual remittances from the definition of applicable information and therefore from data reporting. One commenter requested an ''across the board waiver'' from the reporting requirement for all small medical practices.

Response: We addressed the comment requesting exclusion of manual remittances from the definition of applicable information in the CLFS final rule (81 FR 41053 through 41054). We explained that the statute is clear that applicable information, which is used to set CLFS payment amounts, must be reported for applicable laboratories for a data collection period, and it defines applicable information, in part, as the payment rate that was paid by each private payor for the test during a data collection period and the volume of such tests for each such payor for the data collection period. As such, we stated that we believe the statute does not support selective reporting of applicable information for applicable laboratories. If the laboratory meets the definition of applicable laboratory, the applicable information for that laboratory must be reported. In addition, given that the statute requires applicable information to be reported for applicable laboratories, we do not believe granting an ''across the board waiver'' from the reporting requirements for all small laboratories would be consistent with statute. We believe that the low expenditure threshold would continue to exclude the majority of small laboratories from the applicable laboratory definition and, therefore, from data reporting.

With regard to the commenters suggesting that we implement aggregate reporting, we note that section 1834A(a)(6) of the Act permits the Secretary, beginning with January 1, 2019, to establish rules to aggregate reporting in situations 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. While the agency did not propose or solicit comments on implementing aggregate data reporting, we will take the commenters' suggestion into consideration for future refinements to the CLFS. However, to help reduce administrative burden for the next data reporting period, we will allow reporting entities the option to condense certain applicable information at the TIN-level, instead of reporting for each applicable laboratory individually at the NPI level. We will provide more information regarding the condensed reporting option through subregulatory guidance during the next data collection period.

Comment: One commenter suggested that CMS adopt a 90-day data collection period instead of the current 6-month data collection period to alleviate some of the burden associated with collecting applicable information.

Response: While we did not propose or solicit comments on changing the data collection period, we will take the commenter's suggestion into consideration for future refinements to the CLFS.

Comment: One commenter raised concerns about the integrity of the data reported during the first data reporting period. The commenter mentioned that the CLFS final rule was released just prior to the end of the first data collection period and as a result, laboratories struggled to collect information and submit the required data accurately. The commenter noted that many laboratories still do not have the systems in place to determine the private payor payment rates for each test and the associated volume paid at each rate, therefore exacerbating the potential for inaccurate reporting in the next data reporting period. The commenter was particularly concerned about how inaccurate data affects newer tests in which the volume of services has

remained relatively low as compared to well established laboratory procedures. For instance, because of the low volume of applicable information being reported for Tier 1 and Tier 2 molecular pathology procedures, the commenter stated that any inaccurate data reported has a greater impact on these test codes. The commenter noted that expanding the definition of an applicable laboratory would likely result in additional reporting errors and therefore, did not support any revisions to the definition of an applicable laboratory. Instead, the commenter urged CMS to refine the reporting process and implement measures to safeguard data integrity in future reporting periods. Specifically, the commenter requested that CMS consider implementing a data aggregation system for future data reporting periods, consistent with statutory authority. The commenter noted that a data aggregation system may guarantee more complete reporting and expand the ability of laboratories to report accurate data.

Response: We share the commenter's interest in collecting accurate data. As discussed previously, we are finalizing changes to the definition of applicable laboratory in § 414.502. We did not propose changes to the CLFS data reporting requirements or solicit comments on how to safeguard against inaccurate data. We will consider the issues raised by the commenter for future rulemaking. As noted in response to another comment, for the next data reporting period we will permit the reporting entity to condense applicable information for its applicable laboratories at the TIN level, instead of reporting for each of its applicable laboratories individually, and will issue subregulatory guidance on this topic.

Comment: One commenter stated that in general ''our market based system is flawed'' because it allows companies to profit on people's health. The commenter stated that the CLFS should be based on recovering costs only and not profit. The commenter noted that such approach will lead to a decrease in cost for laboratory testing and a standardization of fees across the industry.

Response: As previously noted, section 1834A of the Act generally requires the payment amount for each CDLT on the CLFS to be based on the applicable information collected from applicable laboratories during a data collection period and reported to us during a data reporting period. Basing CLFS rates on laboratory costs would not be permissible under the statute.

Comment: One commenter stated that uncertainty regarding the definition of an ADLT has discouraged some laboratories from applying for ADLT status, and suggested that we should implement the regulatory requirements in a manner that ''recognizes the uniqueness of the results generated by each precision diagnostic test due to its use of a proprietary algorithm validated in a unique patient cohort.''

Response: We did not propose or solicit any comments regarding changes to the definition of an ADLT, therefore, this comment is not within the scope of this rulemaking.

B. Changes to the Regulations Associated With the Ambulance Fee Schedule

1. Overview of Ambulance Services

a. Ambulance Services

Under the ambulance fee schedule, the Medicare program pays for ambulance transportation services for Medicare beneficiaries under Medicare Part B when other means of transportation are contraindicated by the beneficiary's medical condition and all other coverage requirements are met. Ambulance services are classified into different levels of ground (including water) and air ambulance services based on the medically necessary treatment provided during transport.

These services include the following levels of service:

- For Ground—

++ Basic Life Support (BLS) (emergency and non-emergency).

++ Advanced Life Support, Level 1 (ALS1) (emergency and non-emergency).

++ Advanced Life Support, Level 2 (ALS2).

++ Paramedic ALS Intercept (PI).

++ Specialty Care Transport (SCT).

- For Air—

++ Fixed Wing Air Ambulance (FW).

++ Rotary Wing Air Ambulance (RW).

b. Statutory Coverage of Ambulance Services

Under sections 1834(l) and 1861(s)(7) of the Act, Medicare Part B (Supplemental Medical Insurance) covers and pays for ambulance services, to the extent prescribed in regulations, when the use of other methods of transportation would be contraindicated by the beneficiary's medical condition.

The House Ways and Means Committee and Senate Finance Committee Reports that accompanied the 1965 Social Security Amendments suggest that the Congress intended that—

- The ambulance benefit cover transportation services only if other means of transportation are contraindicated by the beneficiary's medical condition; and

- Only ambulance service to local facilities be covered unless necessary services are not available locally, in which case, transportation to the nearest facility furnishing those services is covered (H.R. Rep. No. 213, 89th Cong., 1st Sess. 37 and Rep. No. 404, 89th Cong., 1st Sess. Pt 1, 43 (1965)).

The reports indicate that transportation may also be provided from one hospital to another, to the beneficiary's home, or to an extended care facility.

c. Medicare Regulations for Ambulance Services

The regulations relating to ambulance services are set forth at 42 CFR part 410, subpart B, and 42 CFR part 414, subpart H. Section 410.10(i) lists ambulance services as one of the covered medical and other health services under Medicare Part B. Therefore, ambulance services are subject to basic conditions and limitations set forth at § 410.12 and to specific conditions and limitations included at §§ 410.40 and 410.41. Subpart H of part 414 describes how payment is made for ambulance services covered by Medicare Part B.

2. Ambulance Extender Provisions

a. Amendment to Section 1834(l)(13) of the Act

Section 146(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), (Pub. L. 110–275, enacted July 15, 2008) amended section 1834(l)(13)(A) of the Act to specify that, effective for ground ambulance services furnished on or after July 1, 2008, and before January 1, 2010, the ambulance fee schedule amounts for ground ambulance services shall be increased as follows:

- For covered ground ambulance transports that originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 3 percent.

- For covered ground ambulance transports that do not originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 2 percent.

The payment add-ons under section 1834(l)(13)(A) of the Act have been extended several times. Most recently, section 50203(a)(1) of the Bipartisan Budget Act of 2018 (BBA) (Pub. L. 115–123, enacted February 9, 2018) amended section 1834(l)(13)(A) of the Act to extend the payment add-ons through