Sections 3105(c) and 10311(c) of the Affordable Care Act amended section 1834(l)(12)(A) of the Act to extend this rural bonus for an additional year through December 31, 2010. In the CY 2011 PFS final rule with comment period (75 FR 73385, 73386 and 73625), we revised § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

Section 106(c) of the MMEA amended section 1834(l)(12)(A) of the Act to extend the rural bonus described above for an additional year, through December 31, 2011. Therefore, in the CY 2012 ESRD PPS final rule (76 FR 70284, 70285 and 70315), we revised § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

Section 306(c) of the TPTCCA amended section 1834(l)(12)(A) of the Act to extend this rural bonus through February 29, 2012; and section 3007(c) of the MCTRJCA further amended section 1834(l)(12)(A) of the Act to extend this rural bonus through December 31, 2012. In the CY 2013 PFS final rule with comment period (77 FR 69140, 69368), we revised § 414.610(c)(5)(ii) to conform the regulations to these statutory requirements.

Subsequently, section 604(c) of the ATRA amended section 1834(l)(12)(A) of the Act to extend this rural bonus through December 31, 2013. Therefore, we are continuing to apply the 22.6 percent rural bonus described above (in the same manner as in previous years), to ground ambulance services with dates of service on or after January 1, 2013 and before January 1, 2014 where transportation originates in a qualified rural area.

This rural bonus is sometimes referred to as the ''Super Rural Bonus'' and the qualified rural areas (also known as ''super rural'' areas) are identified during the claims adjudicative process via the use of a data field included on the CMS-supplied ZIP Code File.

In the proposed rule, we proposed to revise § 414.610(c)(5)(ii) to conform the regulations to the statutory requirement set forth at section 604(c) of the ATRA. We did not receive any comments on this proposal. Accordingly, we are finalizing our proposal to revise § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

This statutory requirement is self-implementing. This provision requires a one-year extension of the rural bonus (which was previously established by the Secretary) through December 31, 2013, and does not require any substantive exercise of discretion on the part of the Secretary.

4. Addition of Section 1834(l)(15) of the Act

Section 637 of the ATRA, which added section 1834(l)(15) of the Act, specifies that the fee schedule amount otherwise applicable under the preceding provisions of section 1834(l) of the Act shall be reduced by 10 percent for ambulance services furnished on or after October 1, 2013, consisting of non-emergency basic life support (BLS) services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section 1881(b)(14)(B) of the Act) furnished other than on an emergency basis by a provider of services or a renal dialysis facility. We proposed to revise § 414.610 by adding paragraph (c)(8) to conform the regulations to this statutory requirement. We did not receive any comments on this proposal. Accordingly, we are finalizing our proposal to revise § 414.610 by adding paragraph (c)(8) to conform the regulations to the statutory requirement described above.

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate decrease, and does not require any substantive exercise of discretion on the part of the Secretary. Accordingly, for the ambulance services described in section 637 of the ATRA furnished on or after October 1, 2013, the fee schedule amount otherwise applicable (both base rate and mileage) is reduced by 10 percent. For further information regarding application of this mandated rate decrease, please see CR 8269.

5. Studies of Ambulance Costs

Section 604(d)(1) of the ATRA provides that the Secretary shall conduct the following studies:

(A) A study that analyzes data on existing cost reports for ambulance services furnished by hospitals and critical access hospitals, including variation by characteristics of such providers of services, with a Report to Congress on such study due by October 1, 2013; and

(B) A study of the feasibility of obtaining cost data on a periodic basis from all ambulance providers of services and suppliers for potential use in examining the appropriateness of the Medicare add-on payments for ground ambulance services furnished under the fee schedule under section 1834(l) of the Act and in preparing for future reform of such payment system, with a Report to Congress due on such study by July 1, 2014.

Further, in conducting the study under paragraph (B) above, section 604(d)(2) of the ATRA directs the Secretary to:

- Consult with industry on the design of such cost collection efforts;
- Explore the use of cost surveys and cost reports to collect appropriate cost data and the periodicity of such cost data collection;
- Examine the feasibility of developing a standard cost reporting tool for providers of services and suppliers of ground ambulance services; and
- Examine the ability to furnish such cost data by various types of ambulance providers of services and suppliers, especially by rural and super-rural providers of services and suppliers.

As noted above, in conducting the study under section 604(d)(1) of the ATRA described in paragraph (B) above, the Secretary is required to consult with industry on the design of such cost collection efforts (see section 604(d)(2)(A) of the ATRA). We used the proposed rule as the instrument to collect information, comments, and ideas from the industry on the design of such cost collection efforts as described above, and on the feasibility of obtaining cost data on a periodic basis from all ambulance providers of services and suppliers for potential use in examining the appropriateness of the Medicare add-on payments for ground ambulance services furnished under the fee schedule under section 1834(l) of the Act and in preparing for future reform of such payment system. We therefore invited public comment on these issues as part of the study we are conducting under section 604(d)(1)(B) of the ATRA.

Several organizations provided detailed comments on the issues described above. We appreciate the commenters' insights and suggestions. We will consider those comments as we perform the study required by section 604(d)(1)(B) of the ATRA and prepare the Report to Congress.

E. Policies Regarding the Clinical Laboratory Fee Schedule

1. Background on the Clinical Laboratory Fee Schedule

Under Medicare Part B, clinical diagnostic laboratory tests furnished on or after July 1, 1984, in a physician's office, by an independent laboratory, or by a hospital laboratory for its outpatients and nonpatients are paid on the basis of the Clinical Laboratory Fee Schedule (CLFS), with certain exceptions. For each Healthcare

Common Procedure Coding System (HCPCS) code, payment is the lesser of:

- The amount of charges billed for the test;
- The fee schedule amount for the state or a local geographic area; or
- A national limitation amount (NLA) (see section 1833(a)(1)(D)(i), (a)(2)(D)(i), (h)(1), and (h)(4)(B) of the Act). The NLA for a clinical diagnostic laboratory test performed after December 31, 1997 is equal to 74 percent of the median of all fee schedules established for that test for that laboratory setting or 100 percent of such median in the case of a clinical diagnostic laboratory test performed on or after January 1, 2001 that the Secretary determines is a new test for which no limitation amount has previously been established (see section 1833(h)(4)(B)(viii) of the Act).

Currently, we update the CLFS amounts annually to reflect changes in the Consumer Price Index for all Urban Consumers (CPI–U) and apply a multi-factor productivity adjustment (see section 1833(h)(2)(A) of the Act). In the past, we also implemented other adjustments or did not apply the change in the CPI–U to the CLFS for certain years in accordance with statutory mandates. We do not otherwise update or change the payment amounts for tests on the CLFS.

For any clinical diagnostic laboratory tests where a new or substantially revised HCPCS code is assigned on or after January 1, 2005, we determine the basis for, and amount of, payment for these clinical diagnostic laboratory tests (see section 1833(h)(8) of the Act and § 414.500 through § 414.509). Once established, however, in most cases, we only have the opportunity to reconsider the basis and/or amount of payment for new tests for one additional year after the basis or payment is initially set. Once the reconsideration process is complete, payment is not further adjusted (except by a change in the CPI–U, the productivity adjustment, and any other adjustments required by statute), regardless of any shift in the actual costs incurred to perform the test.

This lack of an established mechanism to adjust payment amounts is unique among the Medicare payment schedules and systems. Generally, other fee schedules and prospective payment systems are evaluated each year to reflect the changing mix of services provided under that system or schedule and then the system or schedule is adjusted to maintain budget neutrality. Since there is currently no process to make such adjustments for the CLFS, payment amounts are not changed despite changes in technology, which affect the cost of performing the tests. This potentially results in CMS not paying as accurately for these tests. As discussed in the CY 2014 PFS proposed rule (78 FR 43350 through 43352), we proposed to implement a process to adjust payment amounts based on changes in technology. Below, we discuss our proposals regarding this process and, at the end of section III.E.2. of this final rule with comment period, respond to comments about our proposals and finalize our policies.

2. Policies Regarding Technological Changes Under Section 1833(h)(2)(A)(i) of the Act

a. Background on Technological Changes

As discussed in the CY 2014 PFS proposed rule (78 FR 43350 through 43351), there has been a significant amount of technological change in the clinical laboratory area since the implementation of the CLFS. This technological change has led to the increased use of point-of-care testing, brand new tests being developed, and the proliferation of laboratory-developed tests. The Institute of Medicine (IOM) dedicated a chapter of its 2000 report ''Medicare Laboratory Payment Policy: Now and in the Future'' to discussing trends in laboratory technology. The report noted rapid and dramatic innovation in the laboratory sector since the 1980s and remarkable growth in the range and complexity of available tests. The IOM concluded that the introduction of new tests, advances in equipment and testing techniques, and the proliferation of advanced information technology have all made testing more efficient and automated.

Technology has enabled a significant site-of-service shift for many laboratory tests from the laboratory environment to the point of health care delivery. This point-of-care testing has increased since the 1980s, when this type of testing first became available, mainly due to changes in technology which resulted in smaller, cheaper, and more portable test kits that are simple to use. For example, drug abuse testing has become readily available at the point-of-care. Point-of-care testing can be performed in various institutional and community settings but the main objective of such testing is to produce a result quickly, at the place where the patient is receiving care, such as at a physician's office or at a hospital bedside, in order to facilitate decisions about appropriate treatment.

There also are brand new technologies that did not exist when the CLFS was established, most notably the methods that are the basis for many genetic and genomic tests. Many of these methods evolved from the work of the Human Genome Project and subsequent research and development by both the federal government and private firms. The cost of sequencing a genome has dropped dramatically since the early inception of this technology in 2001 from more than $95 million per genome to approximately $5,700 in early 2013 (*http://www.genome.gov/pages/der/sequencing_cost.xlsx*). Early tests in this area were less likely to be covered by Medicare because they were either screening tests or tests for conditions found largely in a pediatric population. As this area has expanded over the past several decades, Medicare has taken on a more prominent role in payment for these services. We expect the number of codes and tests in this area to continue to grow as the technology evolves and more tests become available in the areas of pharmacogenomics, personalized and predictive medicine, and companion diagnostics. Moreover, we expect the costs of these tests to change over time, and we believe that the CLFS ought to be able to better reflect these changes.

We also note the growth in laboratory-developed tests (LDTs) over the years. These proprietary tests are developed by laboratories, which then offer the service of providing the test. Some of the most advanced laboratory tests currently being performed are LDTs which use sophisticated proprietary technology. Many LDTs do not have their own HCPCS codes; instead, they are billed using unlisted codes for which Medicare Administrative Contractors (MACs) establish a payment amount for their local jurisdictions. Prior to 2012, other LDTs were billed to Medicare using ''stacking codes,'' where a laboratory submits a code for each step of the testing process. These ''stacking codes'' were eliminated at the end of 2012 and replaced with new test-specific codes.

The use of unlisted CPT and ''stacking'' codes provided us with limited information about the technology used to perform these tests. However, we know that the number of LDTs has been growing over the years. We also know that multiple laboratories have developed different ways to perform the same test. Further, our recent experience with using a gapfilling methodology to price molecular pathology tests, which can be LDTs, has shown that the costs of performing these tests have decreased since contractors initially established payment amounts for the tests, or compared to the code stack previously billed. Our experience with gapfilling

molecular pathology tests also has shown that there is wide variation in the cost of performing the same test by different laboratories.

We believe that, given the technological changes that have occurred in the laboratory industry over the past several decades and the growth in the number of clinical laboratory tests (for example, we have added approximately 800 new test codes to the CLFS since its inception), it would be appropriate to establish a process to reexamine payment amounts on the CLFS to take into account increased efficiency, changes in laboratory personnel and supplies necessary to conduct a test, changes in sites of service, and other changes driven by technological advances.

Section 1833(h)(2)(A)(i) of the Act requires the Secretary to set the fee schedules for clinical laboratory tests ''for the 12-month period beginning July 1, 1984, adjusted annually (to become effective on January 1 of each year) by, subject to [the multi-factor productivity adjustment], . . . a percentage increase or decrease equal to the percentage increase or decrease in the [CPI–U], . . . and *subject to such other adjustments as the Secretary determines are justified by technological changes''* (emphasis added). Under this authority, in the CY 2014 PFS proposed rule (78 FR 43350 through 43352), we proposed a process under which we would systematically reexamine the payment amounts established under the CLFS to determine if changes in technology for the delivery of that service warrant an adjustment to the payment amount.

b. Definition of Technological Changes

In the CY 2014 PFS proposed rule (78 FR 43351), we proposed to define technological changes as changes to the tools, machines, supplies, labor, instruments, skills, techniques, and devices by which laboratory tests are produced and used. We stated that changes in technology could result in changes to, among other things, the resources required to perform the test (such as the type, volume, or number of supplies or reagents required), the laboratory personnel required to perform the test, and/or the frequency of testing, volume of testing, or site of service (for example, a shift in service site from a specialty laboratory to a physician's office). We believe this broad definition would capture all of the technological changes that could impact the resource inputs for various tests on the CLFS. As we explained in the CY 2014 PFS proposed rule (78 FR 43351 and 43352) and as discussed below, the technological changes for a specific test would be discussed in the proposed rule in which we are proposing to adjust the payment amount for that test, and we would seek public comment on our determination of the technological changes and the proposed payment adjustment. We respond to any comments on the proposed definition at the end of section III.E.2. of this final rule with comment period.

c. The Process

In the CY 2014 PFS proposed rule (78 FR 43351), we proposed that, each year, we would review certain codes on the CLFS, as described in the next section, to determine whether we believe that payment for these codes should be adjusted due to technological changes. For those codes where we determine that payment adjustments should be made, beginning with the CY 2015 PFS proposed rule (which will be promulgated during 2014 and any finalized payment adjustments would affect payments beginning in CY 2015), we would identify the test code, discuss how it has been impacted by technological changes, and propose an associated adjustment to the payment amount for the test code as appropriate to reflect the impact of such technological changes.

We believe such adjustments could be made both to increase fee schedule amounts (for example, in situations where new high cost technologies are employed), and to provide for reductions in existing amounts (for example in situations where technology reduces costs through increased efficiencies). We stated that we expect that most payment amounts would decrease due to the changes in technology that have occurred over the years since the payment amounts were established and the general downward trend of costs once a new technology has had an opportunity to diffuse. A key goal in establishing this review process is to ensure payment accuracy after technological changes; thus, payment amounts could increase or decrease as a result of these reviews.

Under our proposed process, we would list codes that we reviewed for which there was insufficient information to support or establish an adjustment to the payment amount due to technological changes. We also would solicit comment on the technology used to perform any tests we reviewed for possible payment changes, and any relevant cost information. We stated that we expect that we would finalize any payment adjustments in the PFS final rule during 2014, which would affect payments beginning in CY 2015. We proposed that the CPI–U and multi-factor productivity adjustments would be applied after we established the new payment amount through our usual instruction process.

We believe that this proposed process would best allow for the greatest amount of transparency in review and the most structured and consistent opportunity for the public to provide input into the process. We solicited comment on these proposals. We respond to comments on this proposed process at the end of section III.E.2. of this final rule with comment period.

d. Identification and Prioritization of Codes To Be Reviewed

In the CY 2014 PFS proposed rule (78 FR 43351 through 43352), we proposed to review all codes currently on the CLFS. We proposed to start our review by examining the payment amounts for codes that have been on the CLFS the longest and then work our way forward, over multiple years, until we have reviewed all of the codes on the CLFS. We believe that the payment amounts for codes that have been on the CLFS the longest amount of time would be most affected by changes in technology because, in general, technology is most expensive earliest in its life cycle but decreases in cost as the technology matures and diffuses. If during the course of reviewing these individual codes we find that there are additional, newer codes that are clinically and/or technologically similar, we proposed to consider them for review at the same time as we review the older codes because we expect that we would have the same or similar justifications for making payment adjustments to those codes. We stated that we intend to review these codes as quickly as possible but we believe there would be a significant administrative burden associated with such a comprehensive review of the approximately 1,250 codes on the CLFS. We estimated that it would take at least 5 years to review all of the existing codes on the CLFS.

Once we completed our review of the codes currently on the CLFS and made any adjustments necessary due to technological changes, we proposed to review codes added to the CLFS after 2015 that have been on the CLFS for at least 5 years. We also would review codes again that have not been reviewed in the previous 5 years, as time and resources allow. We believe that tests that are less than 5 years old are likely still in their technological infancy and enough time would not have passed to adequately assess any change in technology for those services. Similarly, for previously reviewed codes, we believe that technology likely would not

have changed dramatically in less than 5 years. We solicited public comment on how to prioritize these codes, which we expect to address in future rulemaking on this issue.

After the initial review of the codes currently on the CLFS, we also proposed to allow the public to nominate additional codes for review, including those that had been previously reviewed for technological change. We proposed that the public may nominate only codes that have been on the CLFS for at least 5 years and that have not been reviewed in the previous 5 years. Further, we proposed that the nomination must include an explanation from the nominator of the technological change in the service and the way that change affects its delivery. We would then consider these nominations and, in the **Federal Register** the following year, either propose a payment change based on technological changes or explain why we think such a change is not warranted at that time.

We proposed to codify the proposed definition of technological changes and the process at § 414.511.

We solicited public comment on these proposals. We also solicited comment on alternative approaches to achieving our goal of paying appropriately for laboratory tests by accounting for changes in technology. Finally, we solicited comment on general trends in technology change in the laboratory industry and the health care sector in general. The following is a summary of the comments we received regarding our proposals for the CLFS in the CY 2014 PFS proposed rule:

Comment: Several commenters recommended that CMS reconsider its proposal to review and adjust CLFS payment amounts.

Response: The existing payment amounts on the CLFS have not been changed since they were first implemented (excluding changes for inflation and other statutory adjustments). In some cases, payment amounts have not changed for over 30 years (excluding changes for inflation and other statutory adjustments). Therefore, we believe it is necessary and important to review and adjust payment amounts based on technological changes for tests on the CLFS.

Comment: Several commenters were concerned about CMS developing a transparent process where the public, specifically laboratories, could participate in determining which test codes on the CLFS to revisit for payment purposes and provide input on technological changes with respect to a code being reviewed for adjustment. These commenters suggested that one solution might be some type of advisory committee made up of representatives from the laboratory industry and organized by CMS.

Response: We appreciate the comment and agree that the process to adjust payment amounts for tests on the CLFS based on technological changes should be a transparent one. However, developing a formal advisory committee would be a time-consuming and resource intensive process. We believe that we can accomplish the same purpose by utilizing the annual rulemaking cycle, which includes a comment period where the public can provide information on how the technology for providing clinical diagnostic laboratory tests has changed over time and suggestions for data to support revised payment amounts on particular test codes.

We agree that the public also should participate in determining which test codes should be reviewed. We proposed that, after the initial review of all of the test codes currently on the CLFS concludes, the public could nominate codes for review that have been on the CLFS for at least 5 years and that have not been reviewed in the previous 5 years. We also proposed that the nomination must include an explanation from the nominator of the technological change in the service and the way that change affects its delivery. However, based on these comments and upon further reflection, we are changing our proposal so that nominations are not limited to the time period after the initial review period or to certain types of test codes. Under our process, the public may nominate test codes that are on the CLFS for review during the public comment period to the proposed rule.

As we proposed for situations where the public nominates test codes, the nominator must include an explanation of the technological change in the service and the way the change affects its delivery because this information will assist us in determining whether the test code should move forward through the payment adjustment process. In addition, we are changing our proposal to require the nominator to provide any relevant cost information, as well because this information will assist us in determining an appropriate payment should the test code move forward through the payment adjustment process. CMS will retain the final authority in determining which test codes move forward through the payment revision process because, for example, some test codes may be suggested which do not have enough supporting information to justify payment rate revisions based on changes in technology or more test codes may be suggested for payment rate revisions than can possibly be addressed within one rulemaking cycle.

For those codes identified by the public for review where we determine that payment adjustments based on technological changes should be made, in the following year's proposed rule, we will identify the test code, discuss how it has been impacted by technological changes, and propose an associated adjustment to the payment amount for the test code as appropriate to reflect the impact of such technological changes. We also will list any test codes that the public suggested for review but for which we are not proposing to move forward through the payment revision process and explain why we are not proposing any changes at that time. Finalized payment revisions would take effect the following January 1. For example, test codes suggested during the comment period to the CY 2015 PFS proposed rule and agreed to by CMS for the payment revision process will be addressed through the CY 2016 PFS rulemaking process with finalized payment adjustments being effective January 1, 2016.

Comment: Several commenters, along with MedPAC, stated that, if CMS does implement changes in payment amounts for test codes on the CLFS, CMS should consider data from private insurers, federal insurers, and CMS contractors; however, some commenters suggested that contractor data not be used.

Response: It is our intention to consider data from all available sources in order to evaluate the impact of technological changes on payment amounts. We believe that this will promote fair and equitable fee schedules that reflect current and reasonable payments for laboratory tests. Therefore, we plan to review all data that can be obtained from any source.

Comment: Some commenters, along with MedPAC, suggested that CMS focus on high dollar payments first, while other commenters recommended a focus on codes with rapid spending growth. Some commenters recommended that a different timeframe be implemented instead of the proposed one which limits the ability to review a test code until it has been on the CLFS for at least 5 years. These commenters also believe that it will take longer than 5 years to review all the test codes currently on the CLFS.

Response: In the CY 2014 PFS proposed rule (78 FR 43351 through 43352), we proposed to review all codes

currently on the CLFS and we proposed to start our review by examining the payment amounts for codes that have been on the CLFS the longest and then work our way forward over multiple years until we reviewed all of the codes on the CLFS. We also proposed to review newer codes that were clinically and/or technologically similar to the codes being reviewed. Once we had completed this initial review, which we estimated would take at least 5 years, we proposed to review codes added to the CLFS after 2015 that had been on the CLFS for at least 5 years and would review codes again that had not been reviewed in the previous 5 years, as time and resources allowed. Further, as discussed above, we proposed that the public could nominate additional codes for review after this initial review period that had been on the CLFS for at least 5 years and had not been reviewed in the previous 5 years. We sought comment on these proposals as well as alternative approaches to achieving our goal of paying appropriately for laboratory tests by accounting for changes in technology. Upon further reflection and based on these comments, we are modifying our approach to the identification and prioritization of codes for review.

We agree with the commenters who suggest that our proposal limits the ability to review a test code until it has been on the CLFS for at least 5 years. While we believe that addressing test codes that have been on the CLFS at least 5 years provides ample time for the technology to mature and diffuse, we recognize that there are circumstances that would warrant examining test codes for the payment revision process prior to this time. For example, new technologies could be developed that make it more or less costly to perform a test within a timeframe that is less than 5 years. Consistent with commenters' suggestions, we also believe that we should expand the criteria for identifying and prioritizing test codes for review to include criteria, such as rapid spending growth, high dollar payment, and high volume, as well as the oldest test codes on the CLFS, among other considerations, rather than focusing on the oldest codes currently on the CLFS and codes that have been on the CLFS for at least 5 years. We believe that test codes that are most ripe for review will be test codes where the current payment amounts do not account for changes in technology that have occurred since the test code was added to the CLFS and where the adjustments to the payment amounts will have a significant impact on payments made under the CLFS. We believe that expanding and maintaining flexibility with respect to the criteria will assist us in identifying and prioritizing test codes which are most ripe for revision. We will determine which test codes are most ripe for review based on an analysis of the data for test codes on the CLFS.

Therefore, upon further reflection and based on these comments, we are finalizing a modified approach to identify and prioritize codes that will be reviewed every year. Each year, we will conduct a data analysis of codes on the CLFS to determine which codes should be proposed during the rulemaking cycle for a payment adjustment due to technological changes. This review will involve examining test codes in several different ways, such as examining those that have been on the CLFS the longest, those that are high volume test codes, those that have a high dollar payment, or those that have experienced rapid spending growth, among other considerations. As proposed, if we identify codes that are clinically and/or technologically similar to the ones identified through our data analysis process, we will consider them for review at the same time as we review the related codes. As discussed previously, we also will allow the public to nominate codes for review.

Comment: Some commenters, along with MedPAC, asked that CMS not lower all payments and suggested that CMS must take into consideration the technological changes that may have added costs over the years.

Response: We will not be automatically lowering all payment amounts on the CLFS. Rather, test codes and corresponding payment amounts will be reviewed on a case-by-case basis to determine how changes in technology have affected the cost of the test. As we stated in the CY 2014 PFS proposed rule (78 FR 43351) and above in this final rule with comment period, we believe adjustments could be made to increase fee schedule amounts for certain tests (for example, in situations where new high cost technologies are employed), and to provide for reductions in existing amounts for other tests (for example in situations where technology reduces costs through increased efficiencies). A key goal in establishing this review process is to increase payment accuracy after technological changes; thus, payment amounts could increase or decrease as a result of these reviews.

Comment: Some commenters recommended that CMS proceed through negotiated rulemaking, so that interested stakeholders will have a say in the process.

Response: Similar to what we stated above regarding a formal advisory committee, we believe that using a negotiated rulemaking vehicle would be a time-consuming and resource intensive process. We believe that we can accomplish the same purpose by utilizing the rulemaking process, under which we would propose payment revisions for identified test codes and provide a comment period during which the public could comment prior to the publication of the final rule (which would finalize any payment changes). During the comment period, the public can nominate codes for review, provide information on how the technology for providing clinical diagnostic laboratory tests has changed over time and suggest data to support revised payment amounts for particular test codes. Therefore, our annual rulemaking process will provide the public with ample opportunity to comment and interact with us as the process proceeds. CMS will retain the final authority in determining which test codes move forward through the payment revision process.

Comment: Several commenters suggested that the amount of a payment adjustment should be capped during the first year, and any remaining payment adjustment should be phased in over a number of years so that smaller laboratories or laboratories that offer only a small menu of tests would be minimally disrupted.

Response: While we recognize that laboratories of different sizes or specialties may respond differently to market forces, our goal is to adjust payment amounts for test codes up for consideration in a given year as soon as possible to more accurately reflect the costs of these tests based on changes in technology. Laboratories that may be affected by the examination of a payment amount for any specific test code will have the opportunity to comment through the rulemaking process.

Comment: Many commenters suggested that CMS recognize the difference between large and small laboratories so that small laboratories will not be phased out or forced out of business.

Response: It is not our intention to eliminate or phase out any organization or business. Our goal is to adjust the payment amounts for tests on the CLFS to more accurately reflect the costs of tests based on technological changes, which should result in payment amounts under the CLFS being more commensurate with the current costs of providing these tests.

Comment: Several commenters recommended that CMS send proposed adjustments out to interested parties prior to any final decisions for feedback.

Response: We agree that we need to provide notice and an opportunity to comment on proposed adjustments to the fee schedules due to technological changes to interested parties prior to finalizing these adjustments and we believe that our proposed process, which we are finalizing, does this. Specifically, the rulemaking process would propose payment revisions for the identified test codes and provide a comment period during which the public could comment prior to the publication of the final rule (which would finalize any payment adjustments). Therefore, as proposed, we will utilize the rulemaking process with a comment period so that the public can provide information on how the technology of providing clinical diagnostic laboratory tests has changed over time and suggestions for data to support revised payment amounts on particular test codes.

Comment: Some commenters suggested creating a pilot program, a demonstration project, or competitive bidding for changing the payment amounts for codes on the CLFS.

Response: We believe, similar to our response above concerning either a negotiated rulemaking process or an advisory board, that developing anything formal such as a pilot program, a demonstration project, or competitive bidding would be a time-consuming and resource intensive process. We believe that we can accomplish the same purpose by utilizing the rulemaking process with a comment period where the public can nominate test codes for review, provide information on how the technology for delivering clinical diagnostic laboratory services has changed over time and suggest data to support revised payment amounts on particular test codes.

After considering all of the comments received, we are finalizing our proposal without modification to define technological changes as changes to the tools, machines, supplies, labor, instruments, skills, techniques, and devices by which laboratory tests are produced and used. We are finalizing our proposed process, including the prioritization of codes for review, with modification as discussed above and noted below.

Each year, we will conduct a data analysis of codes on the CLFS to determine which codes should be proposed during the rulemaking cycle for a payment adjustment due to technological changes. This review will involve examining test codes in several different ways, such as examining those that have been on the CLFS the longest, those that are high volume test codes, those that have a high dollar payment, or those that have experienced rapid spending growth, among other considerations. If we identify codes that are clinically and/or technologically similar to the ones identified through our data analysis process, we will consider them for review at the same time as we review the related codes.

For those codes where we determine that payment adjustments should be made, beginning with the CY 2015 PFS proposed rule (which will be promulgated during 2014 and any finalized payment adjustments would affect payments beginning CY 2015), we will identify the test code, discuss how the test has been impacted by technological changes, and propose an associated adjustment to the payment amount for the test code as appropriate to reflect the impact of such technological changes. We will solicit comment on the technology used to perform any tests we reviewed for possible payment changes, and any relevant cost information.

Under our process, the public may nominate test codes that are on the CLFS for review during the public comment period to the proposed rule. Test codes nominated for review by the public must include an explanation from the nominator of the technological change in the service and the way that change affects its delivery as well as any relevant cost information. CMS will retain the final authority in determining which test codes move forward through the payment revision process. For those codes identified by the public for review where we determine that payment adjustments based on technological changes should be made, in the following year's proposed rule, we will identify the test code, discuss how it has been impacted by technological changes, and propose an associated adjustment to the payment amount for the test code as appropriate to reflect the impact of such technological changes. We also will list any test codes that the public suggested for review but for which we are not proposing to move forward through the payment revision process and explain why we are not proposing any changes at that time. Finalized payment revisions would take effect the following January 1. For example, test codes suggested during the comment period to the CY 2015 PFS proposed rule and agreed to by CMS for the payment revision process will be addressed through the CY 2016 PFS rulemaking process with finalized payment adjustments being effective January 1, 2016. The CPI–U and multi-factor productivity adjustments will be applied after we establish the new payment amount through our usual instruction process.

Finally, we are codifying our proposed definition of technological changes and the process at § 414.511 with one technical correction. In § 414.511(a), we are adding the words ''fee schedules,'' which we inadvertently omitted in the proposed rule.

3. Changes in the CY 2014 OPPS/ASC Final Rule With Comment Period

In the CY 2014 PFS proposed rule (78 FR 43352), we notified readers that we were proposing to package payment for certain clinical diagnostic laboratory tests into the Ambulatory Payment Classification (APC) group payment for the significant procedures and services with which those laboratory tests are billed in the CY 2014 OPPS/ASC proposed rule. We discussed this proposal in the section on ''Proposed Changes to Packaged Items and Services'' in the CY 2014 OPPS/ASC proposed rule. For details on the final policy, please see the ''Changes to Packaged Items and Services'' section of the CY 2014 OPPS/ASC final rule with comment period.

F. Liability for Overpayments to or on Behalf of Individuals Including Payments to Providers or Other Persons

1. Background and Statutory Authority

CMS waives recovery of overpayments in certain situations for claims based fee-for-service provider, supplier or beneficiary overpayments in accordance with section 1870 of the Act. Section 1870(b) and (c) of the Act provide a waiver of recovery of provider, supplier or beneficiary overpayments under certain presumptions within a specified timeframe. Section 1870(b) and (c) of the Act allow the Secretary to reduce the specified time period to not less than 1 year if the Secretary finds that such a reduction is consistent with the objectives of the Medicare program. Section 638 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240, enacted January 2, 2013) changed the timeframes associated with section 1870(b) and (c) of the Act.

Section 1870(b) of the Act provides for the waiver of recovery of an overpayment to a provider of services (hereinafter, ''provider'') or other person whenever that provider or other person is ''without fault'' in incurring the overpayment. For purposes of section