DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 423, and 425

[CMS–1600–P]

RIN 0938–AR56

Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This major proposed rule addresses changes to the physician fee schedule and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute.

DATES: *Comment date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 6, 2013.

ADDRESSES: In commenting, please refer to file code CMS–1600–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions for "submitting a comment."

2. *By regular mail.* You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1600–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1600–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT:

Chava Sheffield, (410) 786–2298, for issues related to practice expense methodology and impacts.

Ryan Howe, (410) 786–3355, for issues related to direct practice expense inputs and telehealth services.

Joanna Baldwin, (410) 786–7205, for issues related to misvalued services.

Ken Marsalek, (410) 786–4502, for issues related to the multiple procedure payment reduction.

Heidi Oumarou, (410) 786–7942, for issues related to the revision of Medicare Economic Index (MEI).

Roberta Epps, (410) 786–4503, for issues related to chiropractors billing for evaluation and management services.

Craig Dobyski, (410) 786–4584, for issues related to geographic practice cost indices.

Simone Dennis, (410) 786–8409, for issues related to therapy caps.

Darlene Fleischmann, (410) 786–2357, for issues related to "incident to" services.

Corinne Axelrod, (410) 786–5620, for issues related to "incident to" services in Rural Health Center s or Federally Qualified Health Centers.

Anne Tayloe-Hauswald, (410) 786–4546, for issues related to ambulance fee schedule and clinical lab fee schedule.

Sandra Adams, (410) 786–2982, for issues related to Medicare shared savings program.

Rashaan Byers, (410) 786–2305, for issues related to physician compare.

Christine Estella, (410) 786–0485, for issues related to the physician quality reporting system and EHR incentive program.

Ronke Fabayo, (410) 786–4460 or Jay Blake, (410) 786–9371, for issues related to individual liability for payments made to providers and suppliers and handling of incorrect payments.

Rosemarie Hakim, (410) 786–3934, for issues related to coverage of items and services furnished in FDA-approved investigational device exemption clinical trials.

Jamie Hermansen, (410) 786–2064 or Jyme Schafer, (410) 786–4643, for issues related to ultrasound screening for abdominal aortic aneurysms.

Pauline Lapin, (410)786–6883, for issues related to the chiropractic services demonstration budget neutrality issue.

Andrew Morgan, (410) 786–2543, for issues related to e-prescribing under Medicare Part D.

Michael Wrobleswki, (410) 786–4465, for issues related to value-based modifier and improvements to physician feedback.

Elliot Isaac, (410) 786–4735, for malpractice RVUs and for any physician payment issue not identified above.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

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Acronyms

In addition, because of the many organizations and terms to which we refer by acronym in this proposed rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

AMA RUC American Medical Association/[Specialty Society] Relative [Value] Update Committee
ATRA American Taxpayer Relief Act (Pub. L. 112–240)
BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
CAH Critical access hospital
CF Conversion factor
CPT [Physicians] Current Procedural Terminology (*CPT codes, descriptions and other data only are copyright 2012 American Medical Association. All rights reserved.*)
CY Calendar year
DRA Deficit Reduction Act of 2005 (Pub. L. 109–171)
eRx Electronic prescribing
FFS Fee-for-service
FR **Federal Register**
GPCI Geographic practice cost index
HCPCS Healthcare Common Procedure Coding System
MCTRJCA Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96)
MedPAC Medicare Payment Advisory Commission
MEI Medicare Economic Index
MFP Multi-Factor Productivity
MIEA–TRHCA The Medicare Improvements and Extension Act, Division B of the Tax Relief and Health Care Act (Pub. L. 109–432)
MIPPA Medicare Improvements for Patients and Providers Act (Pub. L. 110–275)
MP Malpractice
MPPR Multiple procedure payment reduction
MMEA Medicare and Medicaid Extenders Act (Pub. L. 111–309)
MMSEA Medicare, Medicaid, and State Children's Health Insurance Program Extension Act (Pub. L. 110–73)
NPP Nonphysician practitioner
OBRA '89 Omnibus Budget Reconciliation Act of 1989
OBRA '90 Omnibus Budget Reconciliation Act of 1990
PC Professional component
PE Practice expense
PE/HR Practice expense per hour
PFS Physician Fee Schedule
PQRS Physician Quality Reporting System
RFA Regulatory Flexibility Act
RIA Regulatory impact analysis
RVU Relative value unit
SGR Sustainable growth rate
TAP Technical Advisory Panel
TC Technical component
TPTCCA Temporary Payroll Tax Cut Continuation Act (Pub. L. 112–78)
VBP Value-based purchasing

Addenda Available Only Through the Internet on the CMS Web Site

The PFS Addenda along with other supporting documents and tables referenced in this proposed rule with comment period are available through the Internet on the CMS Web site at *http://www.cms.gov/PhysicianFeeSched/*. Click on the link on the left side of the screen titled, "PFS Federal Regulations Notices" for a chronological list of PFS **Federal Register** and other related documents. For the CY 2014 PFS proposed rule, refer to item CMS–1600–P. Readers who experience any problems accessing any of the Addenda or other documents referenced in this proposed rule and posted on the CMS Web site identified above should contact Elliot Isaac at (410) 786–4735.

CPT (Current Procedural Terminology) Copyright Notice

Throughout this proposed rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2012 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary and Background

A. Executive Summary

1. Purpose

This major proposed rule would revise payment polices under the Medicare Physician Fee Schedule (PFS) and make other policy changes related to Medicare Part B payment. These changes would be applicable to services furnished in CY 2014.

2. Summary of the Major Provisions

The Social Security Act (Act) requires us to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The Act requires that RVUs be established for three categories of resources: work, practice expense (PE); and malpractice (MP) expense; and that we establish by regulation each year payment amounts for all physicians' services, incorporating geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas. In this major proposed rule, we propose RVUs for CY 2014 for the PFS and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. In addition, this proposed rule includes discussions and proposals regarding:

- Misvalued PFS Codes.
- Telehealth Services.
- Applying Therapy Caps to Outpatient Therapy Services Furnished by CAHs.
- Requiring the Compliance with State law as a Condition of Payment for Services Furnished Incident to Physician and Other Practitioner Services.
- Revising the MEI based on MEI TAP Recommendations.

as part of the study we are conducting under section 604(d)(1)(B) of the ATRA.

E. Proposals 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 currently are paid on the basis of the Clinical Laboratory Fee Schedule (CLFS), with limited 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) (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 (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 (U.S. city average) (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 in accordance with statutory mandates. For example, under section 1833(h)(2)(A)(i) of the Act, we were required to subtract 0.5 percentage points from the CPI–U adjustment for 2009 and 2010. We do not otherwise update or change 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 42 CFR 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, 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 essentially locked in place and do not change when the cost of the test changes. As discussed below, in this proposed rule, we are proposing to implement a process to adjust payment amounts based on changes in technology.

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

a. Background on Technological Changes

There has been a significant amount of technological change in the clinical laboratory area since the implementation of the CLFS, which has resulted in 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, to facilitate decisions about appropriate treatment.

There are also brand new technologies that did not exist when the CLFS was established, most notably genetic and genomic tests. This area of medicine 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 in the 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 (see 77 FR 68994 through 69002 for a thorough discussion of how Medicare pays for these tests). 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.

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 codes; instead, they are billed using unlisted codes for which contractors establish a payment amount. Other LDTs were billed to Medicare using "stacking codes," where a laboratory submits a code for each step of the testing process; however, these "stacking codes" were eliminated at the end of 2012 for molecular pathology tests and replaced with 114 new test-specific codes. These payment processes provide 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 and multiple laboratories have developed ways to perform the same test. Further, our recent experience with using a gap filling methodology to price molecular pathology tests, which are often 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 gap filling molecular pathology tests has also 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 (CMS has added approximately 800 new test codes to the CLFS since its inception), it would be appropriate to establish a process to reconsider 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], [the change in the CPI–U] and *subject to such other adjustments as the Secretary determines are justified by technological changes*" (emphasis added). Under this authority, we are proposing a process under which we will 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. Proposed Definition of Technological Changes

We are proposing 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. 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 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 payment adjustment.

c. Proposed Process

We are proposing 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, 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 expect that most payment amounts will 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 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 rates could increase or decrease as a result of these reviews.

Under our proposed process, we would also list codes that we reviewed but for which there was insufficient information to support or establish an adjustment to the payment amount due to technological changes. We would solicit comment on the technology used to perform any tests we reviewed for possible payment changes, and any relevant cost information. We expect that we would finalize any payment adjustments in the PFS final rule, beginning with the CY 2015 PFS final rule. We are proposing that the CPI–U and multi-factor productivity adjustments would be applied after we establish 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 are soliciting comment on these proposals.

d. Proposed Identification and Prioritization of Codes to be Reviewed

We are proposing to review all codes currently on the CLFS. We are proposing to start our review by examining the 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 are proposing to consider them for review at the same time as we review the older codes because we expect we would have the same or similar justifications for making payment adjustments to those codes. 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 1,250 codes on the CLFS. We are estimating that it would take at least 5 years to review all of the existing codes on the CLFS.

Once we have completed our review of the codes currently on the CLFS and made any adjustments necessary due to technological changes, we are proposing to review codes added to the CLFS after 2015 that have been on the CLFS for at least 5 years. We would also 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 are soliciting 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 are also proposing to allow the public to nominate additional codes for review, including those that had been previously reviewed for technological change. We are proposing 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 are

proposing 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 are proposing to codify the proposed process at 42 CFR 414.511.

We are seeking public comment on these proposals. We also are seeking comment on alternative approaches to achieving our goal of paying appropriately for laboratory tests by accounting for changes in technology. Finally, we are soliciting comment on general trends in technology change in the laboratory industry and the health care sector in general.

3. Proposed Changes in the CY 2014 OPPS/ASC Proposed Rule

In the CY 2014 OPPS/ASC proposed rule, CMS is proposing to package payment for certain clinical diagnostic laboratory tests into the base payment for the Ambulatory Payment Classification (APC). For details on this proposal, please see the "Proposed Changes to Packaged Items and Services" section of the CY 2014 OPPS/ASC proposed rule. Comments on the OPPS proposal should be made to the CY 2014 OPPS/ASC proposed rule. Comments on the proposals in this rule should be made to the CY 2014 PFS proposed rule.

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 one 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 1870 of the Act and this proposed rule, the term "other person" includes practitioners, physicians, and other suppliers.

Section 1870(b) of the Act also establishes circumstances under which a provider or other person is presumed for administrative purposes to be "without fault" for an overpayment. If an overpayment is determined after a specified period of time, a provider or other person is presumed to be "without fault." This presumption is negated, however, if there is evidence to show that the provider or other person was responsible for causing the overpayment.

Section 1870(c) of the Act provides for the waiver of recovery of an overpayment to an individual whenever the individual is "without fault" in incurring the overpayment, and recovery would either defeat the purpose of the Social Security or Medicare programs or would be "against equity and good conscience."

Section 1870(c) of the Act also establishes circumstances under which recovery of an overpayment for an individual is presumed to be "against equity and good conscience." After a specified period of time, recovery of certain overpayments from individuals who are "without fault" is presumed "against equity and good conscience." The overpayments addressed by this provision are payments for items or services for which payment may not be made because of the prohibitions found in section 1862(a)(1) or (a)(9) of the Act. Sections 1862(a)(1) and (a)(9) prohibit payment for, among other things, items and services that are not reasonable and necessary or that are for custodial care.

Section 638 of the ATRA amended the timeframe specified in section 1870(b) of the Act "without fault" presumption from 3 to 5 years so that the presumption of "without fault" only applies if the Medicare claims based fee-for-service overpayment determination for a provider or other person is made subsequent to the fifth year (instead of the third year) following the year in which the notice was sent to such individual that such amount had been paid. Likewise, section 638 of the ATRA amended the timeframe in section 1870(c) of the Act so that the presumption for "against equity and good conscience" for certain types of denials for an individual who is "without fault" only applies if the overpayment determination is made subsequent to the fifth year (instead of the third year) following the year in which notice of such payment was sent to such individual.

These ATRA changes do not affect or change CMS' claims reopening regulation at § 405.980. Specifically, we retain our authority to reopen claims for any reason within one year, for good cause within 4 years, and at any time for fraud or similar fault.

2. Provisions of the Proposed Regulations

We propose to revise § 405.350(c) and § 405.355(b). These proposed revisions would change the timing of the triggering event for the "without fault" and "against equity and good conscience" presumptions. These revisions are being proposed to reflect the revisions to section 1870 of the Act as specified in by section 638 of ATRA.

Specifically, we propose to change the timeframe at § 405.350(c) so that the rebuttable "without fault" presumption for the provider or other person would apply if the Medicare claims based fee-for-service overpayment determination is made subsequent to the fifth year (instead of the third year) following the year in which the notice was sent to such individual that such amount had been paid.

Likewise, we propose to amend the timeframe at § 405.355(b) for the presumption "against equity and good conscience" for certain types of denials for an individual who is "without fault" so that the presumption would apply if the overpayment determination is made subsequent to the fifth year (instead of the third year) following the year in which the notice of payment was sent to the individual.

Additionally, in our review of the current regulation implementing section 1870(c) of the Act, we noted that § 405.355(b) does not clearly reflect the statutory language, which limits the "against equity and good conscience" presumption to overpayments associated with denials under section 1862(a)(1) or (a)(9) of the Act. Accordingly, we propose to update and clarify § 405.355(b) so that it clearly reflects the statutory language by adding that the "against equity and good conscience" presumption would be applicable for an individual who is "without fault" only if the overpayment is related to items and services that are not payable under section 1862(a)(1) or (a)(9) of the Act. In addition, we propose to delete the parenthetical at the end of § 405.355(b) because the regulations referenced no longer exists; those

sections of the regulations were reassigned. (See the October 11, 1989 FEDERAL REGISTER (54 FR 41733).) The modifications we propose to § 405.355(b) makes the references in the parenthetical no longer necessary.

G. Physician Compare Web site

1. Background and Statutory Authority

Section 10331 (a)(1) of the Affordable Care Act, requires that, by no later than January 1, 2011, we develop a Physician Compare Internet Web site with information on physicians enrolled in the Medicare program under section 1866(j) of the Act, as well as information on other eligible professionals who participate in the Physician Quality Reporting System (PQRS) under section 1848 of the Act.

CMS launched the first phase of Physician Compare on December 30, 2010 (*www.medicare.gov/physiciancompare*). In the initial phase, we posted the names of eligible professionals that satisfactorily submitted quality data for the 2009 PQRS, as required by section 1848(m)(5)(G) of the Act.

Section 10331(a)(2) of the Affordable Care Act also requires that, no later than January 1, 2013, and for reporting periods that begin no earlier than January 1, 2012, we implement a plan for making publicly available through Physician Compare information on physician performance that provides comparable information on quality and patient experience measures. We met this requirement in advance of January 1, 2013, as outlined below, and intend to continue to address elements of the plan through rulemaking.

To the extent that scientifically sound measures are developed and are available, we are required to include, to the extent practicable, the following types of measures for public reporting:

- Measures collected under the PQRS.
- An assessment of patient health outcomes and functional status of patients.
- An assessment of the continuity and coordination of care and care transitions, including episodes of care and risk-adjusted resource use.
- An assessment of efficiency.
- An assessment of patient experience and patient, caregiver, and family engagement.
- An assessment of the safety, effectiveness, and timeliness of care.
- Other information as determined appropriate by the Secretary.

As required under section 10331(b) of the Affordable Care Act, in developing and implementing the plan, we must include, to the extent practicable, the following:

- Processes to ensure that data made public are statistically valid, reliable, and accurate, including risk adjustment mechanisms used by the Secretary.
- Processes for physicians and eligible professionals whose information is being publicly reported to have a reasonable opportunity, as determined by the Secretary, to review their results before posting to Physician Compare. This would consist of a 30-day preview period for all measurement performance data that will allow physicians and other eligible professionals to view their data as it will appear on the Web site in advance of publication. Details of the preview process will be communicated on the Physician Compare Initiative page on CMS.gov in advance of the preview period.
- Processes to ensure the data published on Physician Compare provides a robust and accurate portrayal of a physician's performance.
- Data that reflects the care provided to all patients seen by physicians, under both the Medicare program and, to the extent applicable, other payers, to the extent such information would provide a more accurate portrayal of physician performance.
- Processes to ensure appropriate attribution of care when multiple physicians and other providers are involved in the care of the patient.
- Processes to ensure timely statistical performance feedback is provided to physicians concerning the data published on Physician Compare.
- Implementation of computer and data infrastructure and systems used to support valid, reliable and accurate reporting activities.

Section 10331(d) of the Affordable Care Act requires us to consider input from multi-stakeholder groups in selecting quality measures for Physician Compare, which we note we are working to accomplish through a variety of means including rulemaking and various forms of stakeholder outreach. In developing the plan for making information on physician performance publicly available through Physician Compare, section 10331(e) of the Affordable Care Act requires the Secretary, as the Secretary deems appropriate, to consider the plan to transition to value-based purchasing for physicians and other practitioners that was developed under section 131(d) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275, enacted on July 15, 2008).

Under section 10331(f) of the Affordable Care Act, we are required to submit a report to the Congress, by January 1, 2015, on Physician Compare development, and include information on the efforts and plans to collect and publish data on physician quality and efficiency and on patient experience of care in support of value-based purchasing and consumer choice. Initial work on this report is currently underway. Section 10331(g) of the Affordable Care Act provides that any time before that date, we may continue to expand the information made available on Physician Compare.

We believe section 10331 of the Affordable Care Act supports our overarching goals of providing consumers with quality of care information to make informed decisions about their healthcare, while encouraging clinicians to improve on the quality of care they provide to their patients. In accordance with section 10331 of the Affordable Care Act, we intend to utilize Physician Compare to publicly report physician performance results.

2. Public Reporting of Physician Performance Data

Since the initial launch of the Web site, we have continued to build on and improve Physician Compare. In 2013, we launched a full redesign of Physician Compare offering significant improvements including a complete overhaul of the underlying database and a new Intelligent Search feature, addressing two of our stakeholders' primary critiques of the site and considerably improving functionality and usability. The primary source of administrative information on Physician Compare is the Provider Enrollment, Chain, and Ownership System (PECOS); as the sole source of verified Medicare professional information, PECOS remains the primary information source. However, with the redesign, we incorporated Medicare claims information to verify the information in PECOS to ensure only the most current and accurate information is included on the site.

With the redesign, users can now search for Medicare physicians and other healthcare professionals by defining a location—a ZIP code, a city/State combination, an exact address, or landmark—and by entering a medical specialty, health care professional or group practice name, a medical condition, body part, or organ system. The site produces a list of suggested specialties, as defined by the 855i Medicare Enrollment Form, users can choose related to their search term or a list of names, as appropriate.