

of the psychologist's or physician's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report); and 96119 (Neuropsychological testing (e.g., Halstead-Reitan Neuropsychological Battery, Wechsler Memory scales and Wisconsin Card Sorting Test), with qualified health care professional interpretation and report, administered by technician, per hour of technician time, face-to-face), to the list of telehealth services for CY 2011 based on their similarity to other telehealth services.

In the CY 2008 PFS final rule with comment period (72 FR 66251), we stated that we have received conflicting comments and data regarding the appropriateness of furnishing neuropsychological testing via telehealth. While we appreciate the recent request for addition of these same services to the Medicare telehealth services list, we do not believe that these services are similar to services currently on the Medicare telehealth services list and, therefore, we conclude that they would not be appropriate for consideration or addition under category 1. In this year's request for the addition of these services, we received no information to indicate that the diagnostic findings of neuropsychological testing through telehealth are similar to those based upon in-person testing, and therefore, that testing through telehealth does not affect the patient's diagnosis. Therefore, we are not proposing to add neuropsychological testing services to the list of approved Medicare telehealth services for CY 2011.

7. Speech-Language Pathology Services

The Marshfield Clinic submitted a request to add various speech-language pathology services to the list of approved telehealth services for CY 2011. Speech-language pathologists are not permitted under section 1842(b)(18)(C) of the Act to furnish and receive payment for Medicare telehealth services. Therefore, we are not proposing to add any speech-language pathology services to the list of Medicare telehealth services for CY 2011. For further discussion of these services in the context of telehealth, we refer readers to the CY 2005 and CY 2007 PFS proposed and final rules with comment period (69 FR 47512 and 66276, and 71 FR 48995 and 69657).

8. Home Wound Care Services

Wound Care Associates, LLC, submitted a request to add wound care in the home setting to the list of

Medicare telehealth services. A patient's home is not permitted under current statute to serve as an originating site for Medicare telehealth services. Therefore, we are not proposing to add home wound care services to the list of Medicare telehealth services for CY 2011.

D. Summary of CY 2011 Telehealth Proposals

In summary, we are proposing to add the following requested services to the list of Medicare telehealth services for CY 2011:

- Individual and group KDE services (HCPCS codes G0420 and G0421, respectively);
- Individual and group DSMT services, with a minimum of 1 hour of in-person instruction to be furnished in the year following the initial DSMT service to ensure effective injection training (HCPCS codes G0108 and G0109, respectively);
- Group MNT and HBAI services (CPT codes 97804, and 96153 and 96154, respectively);
- Subsequent hospital care services, with the limitation for the patient's admitting practitioner of one telehealth visit every 3 days (CPT codes 99231, 99232, and 99233); and
- Subsequent nursing facility care services, with the limitation for the patient's admitting practitioner of one telehealth visit every 30 days (CPT codes 99307, 99308, 99309, and 99310).

Furthermore, we are proposing to revise § 410.78(b) and § 414.65(a)(1) accordingly. Specifically, we are proposing to add individual and group KDE services, individual and group DSMT services, group MNT services, group HBAI services, and subsequent hospital care and nursing facility care services to the list of telehealth services for which payment will be made at the applicable PFS payment amount for the service of the practitioner. In addition, we have reordered the listing of services in these two sections and removed "initial and follow-up inpatient telehealth consultations furnished to beneficiaries in hospitals and SNFs" in § 410.78(b) because these are described by the more general term "professional consultations" that is in the same section. Finally, we are continuing to specify that the physician visits required under § 483.40(c) may not be furnished as telehealth services.

V. Provisions of the Patient Protection and Affordable Care Act of 2010

The following section addresses certain provisions of the Patient Protection and Affordable Care Act (Pub. L. 111-148), enacted on March 23,

2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) enacted on March 30, 2010 (collectively known as the Affordable Care Act (ACA)).

A. Section 3002: Improvements to the Physician Quality Reporting System

Section 3002 of ACA makes a number of changes to the Physician Quality Reporting Initiative (PQRI), including authorizing incentive payments through 2014, and requiring a penalty beginning in 2015, for eligible professionals who do not satisfactorily submit quality data. For a more detailed discussion of the provisions of section 3002 of the ACA, please refer to section VI.G.1. of this proposed rule.

B. Section 3003: Improvements to the Physician Feedback Program and Section 3007: Value-based Payment Modifier Under the Physician Fee Schedule

1. Background

As required under section 1848(n) of the Act, as added by section 131(c) of MIPPA, we established and implemented by January 1, 2009, the Physician Resource Use Measurement & Reporting (RUR) Program for purposes of providing confidential reports to physicians that measure the resources involved in furnishing care to Medicare beneficiaries. Section 1848(n) of the Act also authorizes CMS to include information on the quality of care furnished to Medicare beneficiaries by a physician or group of physicians.

We are continuing a phased implementation of the program. Phase I was discussed in the CY 2010 proposed and final rules (74 FR 33589, and 74 FR 61844, respectively), and has been completed. Phase I consisted of several activities including extensive data analysis to inform decisions about topics such as measures, attribution, and risk adjustment and formative testing of report design with practicing physicians. We concluded Phase I by sending to individual practicing physicians in 12 geographic areas¹ several hundred reports that contained per capita and episode-based cost information.

Phase I of the Program focused on providing confidential feedback on resource use measures. Section 1848(n)(1)(A)(iii) of the Act states that the Secretary may also include information on the quality of care

¹ The 12 geographic areas are: Boston, MA, Syracuse, NY, Northern New Jersey, Greenville, SC, Miami, FL, Little Rock, AR, Indianapolis, IN, Cleveland, OH, Lansing, MI, Phoenix, AZ, Seattle, WA, and Orange County, CA.

furnished to Medicare beneficiaries by physicians (or groups of physicians) in the feedback reports. We believe that providing physicians with feedback on both quality and cost is consistent with the direction of other CMS value based purchasing (VBP) initiatives. As a result, we decided to include quality measures in Phase II of the program and, in particular, we considered measures used in PQRI and claims-based measures such as GEM measures (74 FR 61846).

Section 1848(n)(1)(A)(ii) also states that the Secretary may provide reports at the physician group level. Accordingly, as part of Phase II of the program, we will also include reporting to group practices, defined as more than one physician practicing medicine together (74 FR 61846). In addition, we noted that the definition applies to the following types of physician groups: (1) Formally established single or multi-specialty group practices; (2) physicians practicing in defined geographic regions; and (3) physicians practicing within facilities or larger systems of care (74 FR 61846). As we continue with Phase II, we plan to report to both physician group practices and their affiliated practitioners, recognizing that many physicians practice in arrangements other than solo practices. We believe that using both group and individual level reporting will also allow us to gain experience with the sample size issues that arise when individual physicians have too few Medicare beneficiaries with specific conditions to generate reliable information. (See the CY 2010 final rule with comment period (74 FR 61844) for a detailed discussion of plans for Phase II.)

2. Effect of the ACA of 2010 on the Program

The ACA contains two provisions relevant to the RUR program. Section 3003 continues the confidential feedback program and requires the Secretary, beginning in 2012, to provide reports that compare patterns of resource use of individual physicians to other physicians. In addition, section 3007 of the ACA requires the Secretary to apply a separate, budget-neutral payment modifier to the Fee-For-Service physician fee schedule payment formula. The payment modifier, which will be phased in beginning January 1, 2015 through January 1, 2017, will provide for differential payment under the fee schedule to a physician or groups of physicians, and later, possibly to other eligible professionals, based upon the relative quality and cost of care of their Medicare beneficiaries.

Accordingly, our goal is to have Medicare physicians receive a confidential feedback report prior to implementation of the payment modifier. We view these two provisions as complementary, as we expect the work done for the confidential feedback program under section 3003 of the ACA will inform our implementation of the payment modifier under section 3007 of the ACA. The approach used in the confidential feedback reports will serve as the foundation for implementing the payment modifier. Specifically, throughout future phases of reports under the RUR program, we will continue to enhance our measures and methods and improve the content of the reports based on both our research and the feedback of stakeholders before the payment modifier begins to affect physician payments in 2015.

We plan to engage in a large-scale effort to garner widespread stakeholder involvement with regard to how we continue to build and expand the confidential feedback program and transition to implementation of the payment modifier. We recognize that such a payment modifier may have an impact on the delivery of care to Medicare beneficiaries. Reports that will be produced in the future based on changes as a result of section 3003 of the ACA will contain both cost and quality data, and work done to improve these reports with regard to fair and actionable measures in each of these domains will aid our decision making in how to apply the payment modifier. We intend to seek stakeholder input on various aspects of program design, including cost and quality measures, methodologies for compositing measures, and feedback report content and delivery. Such feedback may be gathered through rulemaking, open door forums, or other mechanisms.

3. Phase II Proposed Changes

We anticipate that reports in Phase II of the RUR Program will be distributed in the fall of 2010. We are proposing, however, several changes to the program parameters for Phase II that were finalized in prior rules. First, we plan to discontinue our use of commercially-available proprietary episode grouping software. In particular, section 3003 of the ACA requires that the Secretary develop a Medicare-specific episode grouper by January 1, 2012, the details of which must be made public. This grouper will address the limitations found in the proprietary software.

We recognize that episode-specific cost information is meaningful and actionable for physicians, and we plan to provide such information in feedback

reports after the public grouper software is developed. Prior to that, we may consider other potential interim options for grouping to provide such information. We believe that our use of proprietary episode grouping software in previous phases of the program had limitations. These software products were not intended for use with Medicare claims data, and we discovered several problems with the data outputs. Specifically, the groupers do not work well to create episodes for beneficiaries with multiple chronic conditions, which is a significant portion of Medicare beneficiaries.

For example, when a beneficiary with a chronic disease is hospitalized for an acute condition, that beneficiary most likely also receives treatments unrelated to the condition for which he or she is hospitalized, but related to the chronic disease. The groupers, which are proprietary and often referred to as "black boxes," do not enable users to understand the coding to determine how to accommodate these issues. Therefore, CMS had to make several decisions about how to pre-process the claims data so that the groupers could recognize and attempt to deal with these issues in the clinical grouping logic. After report production in Phase I, we discovered several problems with the pre-processing, which resulted in inaccurate episode cost information being disseminated.

Until a Medicare-specific episode grouping software is developed, we plan to produce reports for Phase II that contain per capita cost information. More specifically, instead of episode-specific cost information, we plan to provide overall per capita cost information, as well as per capita cost information for those beneficiaries with five common chronic diseases: (1) Diabetes, (2) congestive heart failure, (3) coronary artery disease, (4) chronic obstructive pulmonary disease, and (5) prostate cancer. This information will not be specific to the cost of treating the disease itself, but will provide total Part A/B per capita cost information, as well as service category breakdowns, for treating the subset of attributed beneficiaries with that disease.

Second, while commenters have been generally supportive of including PQRI measures in the reports, we propose not including data from PQRI in the reports. The current support contractor for this program has only 2007 PQRI data. This was the first year of PQRI, and participation was still quite low. Because of the low number of physicians reporting under PQRI, and because providers have the flexibility to choose which measures to report under

PQRI, we believe it would be difficult to make meaningful peer comparisons for purposes of these reports. Instead, for Phase II, we propose using the claims-based measures developed by CMS in the Generating Medicare Physician Quality Performance Measurement Results (GEM) project.² This is a core set of 12 process quality measures that can be calculated using only administrative claims data. However, in future phases of the program, we intend to explore the possibility of linking this program to the HITECH incentive program for meaningful use of electronic health records, and the group practice reporting option in PQRI. Both of these programs offer measures and measure sets, as well as methods of reporting data which may be more conducive to meaningful peer comparisons among physicians.

Third, we propose to distribute reports electronically in Phase II, by leveraging the infrastructure used to distribute PQRI feedback reports. This infrastructure will enable groups to utilize an electronic portal to download their Phase II reports. Individual practitioners will be able to contact their MACs/fiscal intermediaries to receive an e-mailed copy of their reports. We have received feedback from physicians that the reports distributed in Phase I were too long and cumbersome to manage in hard copy. Our intent is a condensed report with electronic dissemination that allows for easier navigation. We are seeking public comment on the above proposals.

4. Implementation of Sections 3003 and 3007 of the ACA

The Affordable Care Act provisions that we mention above contain several important implementation dates. In addition to developing an episode grouper by January 1, 2012, we are required to publish the cost and quality measures we intend to use in determining the payment modifier to be effective on January 1, 2012. We are also required to begin implementing the program parameters through rulemaking in 2013. The payment modifier is effective on January 1, 2015, with a phased implementation so that all physicians paid under the physician fee schedule will be subject to the modifier by January 1, 2017. On or after January 1, 2017, we have the authority to also apply the payment modifier to other eligible professionals.

In anticipation of implementing sections 3003 and 3007 of the ACA, we intend to perform extensive data analysis and research, and to seek

stakeholder input on issues related to cost and quality measures so that we can be prepared to publish, by January 1, 2012, those measures we intend to use for the payment modifier. We intend for the work done in determining measures for use in the payment modifier to inform the continued dissemination of confidential feedback reports to both individual physicians and physician groups. Specifically, the measures chosen for use in the payment modifier will be candidates for inclusion in future phases of the confidential feedback reports.

As mentioned above, Phase I included reports to several hundred physicians. In Phase II we anticipate disseminating reports to about 40 large physician groups and the approximately 2,000 physicians affiliated with those groups. We anticipate future phases of the reports to include additional dissemination to increasing numbers of practitioners and groups such that virtually every applicable Medicare practitioner receives a report prior to implementation of the payment modifier.

5. Comments Sought on Specific Statistical Issues Related to the ACA Sections 3003 and 3007

We recognize that there are many important decisions to be made when implementing a program that compares physicians to their peers, especially when such information can lead to differential payment. Since the inception of the RUR program, all data have been price standardized which includes accounting for geographic adjustments. We have identified important statistical issues in previous rules, and as we have done in previous rules, CMS seeks input on several of these topics as they relate to future phases of reports. These include, but are not limited to: risk adjustment; attribution; benchmarking; peer groups; minimum case sizes; cost and quality measures; and compositing methods. To date, the public comments we have received have not led us to a single methodology to propose for dealing with any of these issues. Therefore, we do not make formal proposals in this proposed rule. Specific parameters of the RUR program are based on the most current information we have available to us. These parameters will continue to evolve and we will continue to evaluate them as the state of the art in these areas continues to improve. Therefore, we seek public comment on these issues.

a. Risk Adjustment

The cost data used in Phase I will be risk adjusted. For the per capita costs,

we used the Hierarchical Condition Categories (HCC) model developed for risk adjustment in Medicare Advantage plans. This model takes into account beneficiary characteristics such as age, sex, and Medicaid status, and then predicts costs for beneficiaries based on their unique mix of health conditions. Several other socioeconomic factors, such as the median income per capita in the county where the physician practices, were used. For the episode costs, we used the risk adjustment/severity levels in the proprietary grouper software.

The cost data in Phase II are risk adjusted using the HCC model, but excluding the additional socioeconomic factors such as the median income per capita in the county where the physician practices, as mentioned above. Regression analyses indicated that these additional socioeconomic factors did little to improve the fit of the model, so we will not include them. And since there are no episode-based costs in Phase II—only annual per capita costs—the HCC model will be the only method used. Other methods of risk adjustment exist that we have not used, such as the CC (complications and comorbidities) and MCC (major complications and comorbidities) indicators implemented in the 2008 MS-DRG system.

The quality data included in Phase II will not be risk adjusted because the GEM measures are all clinical process measures, and it is generally accepted that such measures need not be risk adjusted. Beneficiaries should receive the indicated preventive services (for example, breast cancer screening) regardless of their demographic characteristics or presence or absence of health conditions.

We seek comment on the appropriate method for risk adjusting cost data, as well as our reasoning for not risk adjusting clinical process quality measures.

b. Attribution

Deciding which physician(s) is/are responsible for the care of which beneficiaries is an important aspect of measurement. CMS must strike a balance between only attributing cost information to physicians for the services they personally delivered, and attributing costs to physicians based on a more encompassing view of the services provided to each beneficiary so as to encourage better care coordination and accountability for patient outcomes.

There are several methods that are generally used for attributing beneficiaries' costs to physicians for the purposes of measuring and comparing

² <http://www.cms.gov/GEM>.

performance. In Phase I, we used two different attribution methodologies. Half of the reports used the “multiple-proportional” attribution, in which a beneficiary’s costs were summed, and then divided among the physicians who treated that beneficiary in the same proportion as their share of evaluation and management (E&M) services provided. The other half of the reports used the “plurality-minimum” method, in which a beneficiary’s entire cost (either for the episode or for the year) was attributed to the physician who performed the plurality of the E&M services, subject to a minimum percentage (in that case, 10 percent).

In Phase II reports, we plan to use the “plurality-minimum” method with a minimum percentage threshold of E&M services of 20 percent for individual physicians and a minimum percentage threshold of E&M services of 30 percent of the E&M services for physician group level reports. These minimum threshold determinations were based on our analysis of the claims data. We recognize that other attribution methods exist, which may be either more or less appropriate given the aspect of care one is measuring. For example, it may be desirable to attribute the entire cost of a surgical episode to the performing surgeon. Another method for attributing costs is referred to as “multiple-even,” in which the entire beneficiary’s cost is attributed to multiple physicians who treated the beneficiary.

We seek comment on the topic of attribution methodologies, including both of those we have already used in the program, as well as others that may or may not be mentioned here.

c. Benchmarking and Peer Groups

Determining the relevant comparisons to make among physicians is also an important policy aspect of the program. CMS’ research conducted in Phase I of the program indicated that physicians prefer to be compared only to those physicians most like them (that is, the narrowest peer group). We recognize the importance of fair comparison, but are also faced with the challenge that very narrow peer groups are most often not large enough to make statistically significant comparisons.

The individual-level reports in both phases of the program have contained, or will contain, two peer group comparisons: (1) Physicians in the same specialty in the same geographic area; and (2) physicians in the same specialty across all 12 geographic areas. In each of these peer groups, a physician is shown where he or she falls on a distribution that specifically identified the 10th, 50th, and 90th percentiles.

These benchmarks were finalized on an interim basis in the CY 2010 proposed rule (74 FR 33589).

In determining applicability for episode measures in Phase I, we used a statistical reliability test. For per capita measures in Phase I, a physician had to have 20 or more beneficiaries to be measured and compared. There was no minimum peer group size requirement.

The original MIPPA mandate requires CMS to make comparisons among physicians on cost, and gives the Secretary the authority to include comparisons on quality. The use of quality measures in the program was finalized in the CY 2010 final rule (74 FR 61846). In Phase II, comparisons with appropriate peer groups will be made for both cost and quality. Phase II reports will be provided only to those physicians that have 30 or more patients for each of the cost measures. For the quality measures, we plan to use the measure specifications in the GEM project to define minimum case sizes, which are at least 11 beneficiaries. We also plan to impose a minimum peer group size of 30 in Phase II for both the cost and quality measures. A minimum sample size of 30 is generally accepted in the research community as the minimum sample size to represent a group and make comparisons.

We seek comment on the most appropriate and relevant peer groups for comparison, including the appropriate minimum case sizes and minimum peer group sizes. We are also interested in methodologies that can account for small case sizes.

d. Cost and Quality Measures and Compositing Methods

As mentioned above, and in previous rules, section 1848(n)(1)(A)(ii) of the Act gives the Secretary the authority to include both cost and quality information in the feedback reports. In Phase I, we chose to use only cost information, and used both per capita and episode cost measurements. As mentioned above, we previously finalized the use of quality measures in Phase II (74 FR 61846), but propose to discontinue our use of episode cost measurements. We have yet to include any composite measures of cost or quality in the feedback reports.

Section 3007 of the ACA requires CMS to pay physicians differentially based on a modifier derived with composites of both quality and cost measures. Accordingly, we will need to devise a methodology in the future for compositing cost measures and quality measures, including considering, among other things, possible methodologies to develop a single score. In the future,

episode-based cost measures developed using the public Medicare-specific episode grouper software also may be considered in developing a composite score. Other domains of measures that may be considered include patient-level utilization statistics (for example, emergency department visits per 1,000 patients) and structural measures such as whether a provider has adopted an electronic health record. We recognize that measure composites are methodologically and operationally complex and, therefore, we are seeking comment on this topic.

We plan to continue a phased approach in the future. Although we will continue to move from phase-to-phase, any substantive changes to the RUR program will be implemented through rulemaking. We also anticipate continuing to gather feedback from stakeholders about the important data-driven policy topics that affect the feedback reports.

C. Section 3102: Extension of the Work Geographic Index Floor and Revisions to the Practice Expense Geographic Adjustment Under the Medicare Physician Fee Schedule, and Protections for Frontier States as Amended by Section 10324

Section 1848(e)(1)(E) of the Act (as amended by section 3102(a) of the ACA) extends application of the 1.0 work GPCI floor for services furnished through December 31, 2010. In addition, section 1848(e)(1) of the Act (as amended by section 3102(b) of the ACA) specifies that for CY 2010 and CY 2011, the employee wage and rent portions of the PE GPCI must reflect only one-half of the relative cost differences for each locality compared to the national average and includes a “hold harmless” provision for any PFS locality that would receive a reduction to its PE GPCI resulting from the limited recognition of cost differences. Section 1848(e)(1) of the Act (as amended by section 3102(b) of the ACA) also requires an analysis of the current methods and data sources used to determine the relative cost differences in office rent and employee wages compared to the national average and the cost share weights assigned to each PE GPCI component: Employee wages, office rent, and supplies. Finally, section 1848(e)(1) of the Act (as amended by section 3102(b) of the ACA) requires the Secretary to make appropriate adjustments to the PE GPCI by no later than January 1, 2012. In addition, section 1848(e)(1) of the Act (as amended by section 10324(c) of the ACA) establishes a 1.0 PE GPCI floor for services furnished in frontier states effective January 1, 2011. The