



Association of Community Cancer Centers

## **Summary of Selected Provisions of the Medicare Physician Fee Schedule Final Rule for 2011**

The Centers for Medicare & Medicaid Services (CMS) released the Medicare Physician Fee Schedule (PFS) final rule for calendar year (CY) 2011 (“Proposed Rule”) on November 2, 2010.<sup>1</sup> It will be published in the Federal Register on November 29, 2010. The Final Rule discusses several changes that will have a significant effect on payment for cancer care. CMS will accept comments on certain portions of the Final Rule until January 3, 2011.

### Highlights of the Final Rule:

The Final Rule will:

- Reduce physician payment rates in 2011 by an additional projected 10.1 percent, in addition to the 23 percent reduction that was scheduled to go into effect in December 2010, under the sustainable growth rate (SGR) formula.
- Continue the second year of a four-year transition to practice expense (PE) relative value units (RVUs) calculated using Physician Practice Information Survey (PPIS) survey data.
- Change the utilization rate for determining PE RVUs for diagnostic imaging equipment priced over \$1 million and expand the list of services to which the higher equipment utilization rate assumption applies.
- Identify and revise potentially misvalued services under the PFS.
- Expand the imaging multiple procedure payment reduction (MPPR) policy by increasing the reduction from 25 percent to 50 percent and extending it to multiple imaging services provided not only within the same family of codes, but across such families, as well as add four additional CT Current Procedural Terminology (CPT) codes to the policy.
- Create a refined process for regularly updating the prices for equipment and supplies under the PFS and discuss use of prices from the General Services Administration (GSA) medical supply schedule to update inputs for high-cost supplies.
- Rebase and revise the Medicare Economic Index (MEI).
- Address average sales price (ASP) issues, including ASP-based reimbursement rates for biosimilars, carry-over ASPs, partial quarter ASP data, treatment of overfill in the ASP calculation, and Widely Available Market Price (WAMP) / Average Manufacturer Price (AMP) substitution for ASP.
- Change the policy regarding requisitions for clinical laboratory tests.

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<sup>1</sup> Centers for Medicare & Medicaid Services, Department of Health and Human Services, Final Rule with Comment Period, Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011 (Display Copy posted Nov. 2, 2010), *available at* [http://www.ofr.gov/OFRUpload/OFRData/2010-27969\\_PI.pdf](http://www.ofr.gov/OFRUpload/OFRData/2010-27969_PI.pdf). (hereinafter “Final Rule, Display Copy”).

- Implement changes to the Physician Quality Reporting Initiative (PQRI) and the Physician Resource Use Measurement and Reporting (RUR) Program under the Patient Protection and Affordable Care Act (PPACA), as amended by the Health Care and Education Reconciliation Act of 2010 (HCERA).<sup>2</sup>
- Amend the Electronic Prescribing (eRx) Incentive Program to encourage significant expansion of the use of electronic prescribing by authorizing a combination of financial incentives and payment adjustments, including a mechanism for imposing statutorily-required penalties for the failure to successfully e-prescribe beginning in 2012.
- Implement numerous provisions of PPACA, including removing barriers to preventative benefits, creating incentive payments for major surgical procedures furnished in health professional shortage areas (HPSAs), and implementing disclosure requirements for in-office ancillary services.

The cumulative effect of the Final Rule on total Medicare payments to physicians involved in cancer care will be:<sup>3</sup>

Specialty	Allowed Charges (millions)	Combined Impact (Transition)	Combined Impact (Full)
Hematology/Oncology	\$1,912	0%	-2%
Radiation Oncology	\$1,939	-1%	-7%
Radiology	\$5,052	-10%	-14%

### Conversion Factor

CMS estimates that the reduction in the SGR will be 13.4 in 2011. After other adjustments are made to the conversion factor, including an adjustment to offset increases in payment due to the rebasing of the MEI, the conversion factor for 2011 is \$25.5217, 10.1 percent less than the conversion factor scheduled to be in effect in December and 30.7 percent less than the conversion factor in effect from June to November, 2010.<sup>4</sup>

### PE RVUs

Practice Expense (PE) is the “portion of the resources used in furnishing the service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages but excluding malpractice expenses.”<sup>5</sup> The PE RVUs are determined by calculating both direct and indirect physician practice resources involved in furnishing each service.

Transition to PPIS Survey Data: Indirect practice expenses are determined based on survey data. CY 2011 is the second year of the four-year transition to the PE RVUs calculated

<sup>2</sup> Together these Acts are referred to as “PPACA” for purposes of this summary.

<sup>3</sup> Final Rule, Display Copy at 1428-29.

<sup>4</sup> Id. at 378.

<sup>5</sup> Id. at 56.

using the PPIS data. Consistent with the approach taken in CY 2010, the CY 2011 PE RVUs will be a “50/50 blend of the previous PE RVUs based on the SMS and supplemental survey data and the new PE RVUs developed using the PPIS data.”<sup>6</sup> However, there are certain services that are not subject to this transition or to use of the PPIS data at all:

- Reductions in PE RVUs for diagnostic imaging equipment priced over \$1 million attributable to the change to an equipment utilization rate assumption as described below.
- CMS’s continued use of medical oncology supplemental survey data submitted in 2003 for medical oncology, hematology, and hematology/oncology.
- CMS’s continued use of supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), blended with supplemental survey data from the American College of Radiology (ACR).
- For CY 2011, CMS will use a revised PE/HR of \$479.81 for IDTFs, consistent with the policy to update indirect PE/HR values from prior supplemental survey data that CMS is continuing to use in order to put these data on a comparable basis with the PPIS data.
- CMS will continue use of previous crosswalks for specialties that did not participate in the PPIS.

Alternative Data Sources: The Medicare Payment Advisory Commission (MedPAC) recommended that “CMS should consider alternatives to collecting specialty-specific cost data or options to decrease the reliance on such data.”<sup>7</sup> CMS agreed and accepted comments on this proposal in the CY 2010 PFS final rule with comment period, in particular alternatives for collecting specialty-specific cost data or options to decrease reliance on such data. One alternative that was proposed by MedPAC was to eliminate the use of indirect PE/HR data in the last step of establishing the indirect cost portion of the PE RVUs. While CMS did not propose a broad methodological change or broad data collection effort in the Proposed Rule, the agency invited comments on its summary of the issues raised by commenters on the CY 2010 PFS final rule.<sup>8</sup> In the Final Rule, CMS noted that “[w]hile to date, no stakeholders have presented a comprehensive overall alternative methodology,” CMS remains interested in “potential novel or refined approaches” and is “welcome more limited suggestions for improvements to our current PE methodology or future practice expense information collection activities.”<sup>9</sup>

Equipment Utilization Rate: Pursuant to section 3135(a) of PPACA, the Final Rule alters the methodology for determining PE RVUs for diagnostic imaging equipment priced over \$1 million to apply an equipment utilization rate of 75 percent, a reduction from the transitional utilization rate of 90 percent for such equipment adopted in CY 2010.<sup>10</sup> In addition, as proposed, CMS will “expand the list of services to which the higher equipment utilization rate assumption applies to include all other diagnostic imaging services that utilize similar expensive CT and

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<sup>6</sup> *Id.* at 62.

<sup>7</sup> *Id.* at 67.

<sup>8</sup> This rule and comments to it are available for public review at [www.regulations.gov](http://www.regulations.gov) by entering “CMS-1413-FC” in the search box on the main page.

<sup>9</sup> Final Rule, Display Copy at 71.

<sup>10</sup> *Id.* at 82. The equipment utilization rate assumption for other diagnostic imaging equipment remained at 50 percent.

MRI scanners.”<sup>11</sup> The additional 24 CPT codes are predominantly diagnostic computed tomographic angiography (CTA) and magnetic resonance angiography (MRA) procedures. PPACA requires that this adjustment be applied in a non budget-neutral manner. The associated PE RVUs will not be subject to the PPIS data transition as discussed above.

Health Care Common Procedure Coding System (HCPCS) Code Specific PE Proposals:  
The Proposed Rule makes a number of HCPCS Code-Specific PE proposals for 2011. Those relevant to cancer care include the following:

- *Cobalt-57 Flood Source:* As proposed, CMS will change the useful life input of the Cobalt-57 flood source (CMS Equipment Code ER001) from the current five years to two years. This change is based on stakeholders’ estimates of approximately 271 days for the source’s half life as well as materials that marketing the source for a useful life of two years.<sup>12</sup>
- *Equipment Duplication:* As proposed, CMS will remove duplicate items from those CPT codes with duplicate equipment inputs in the PE database. These include the removal of equipment code EF014 (light, surgical) from CPT 19302 (P-mastectomy w/ln removal) and the removal of equipment codes ED005 (camera, digital system, 12 megapixel (medical grade)), EF031 (table, power), and EQ168 (light, exam) from CPT 19361 (Breast reconstr w/ lat flap).<sup>13</sup> In response to comments, CMS will transfer the duplicate surgical light code (EF014) to CPT code 19304 (mastectomy, subcutaneous).
- *Supply Price Inputs Based on Unit Prices and Quantities:* CMS has identified minor errors in total price inputs for a number of supply items due to mathematical mistakes in multiplying the item unit price and the quantity used in particular CPT codes for the associated services and, as proposed, CMS will modify the direct PE database accordingly. CPT codes affected by these revisions include several drug and chemotherapy administration codes, including 96360, 96365, 96366, 96367, 96369, 96371, 96372, 96374, 96375, 96401, 96402, 96409, 96411, 96413, 96417, 96445, and 96542.<sup>14</sup> Notably, the Proposed Rule contained a calculation error with respect to these revisions that has been corrected in the Final Rule.
- *64-Slice CT Scanner and Software:* The American Medical Association’s Relative Value Update Committee (AMA RUC) submitted an updated recommendation regarding the correct pricing of the 64-Slice CT scanner and its accompanying software. The proposed CY 2011 direct PE database has been modified in accordance with the updated price input as a result of this recommendation. These changes affect CPT Codes 75571, 75572, 75573, and 75574.<sup>15</sup>
- *Radiographic Fluoroscopic Room:* As proposed, CMS will remove the radiographic fluoroscopic room (CMS Equipment Code EL014) as a direct PE from CPT codes 64420 (Injection, anesthetic agent; intercostal nerve, single), 64421 (Injection, anesthetic agent; intercostal nerves, multiple, regional block); and 64620 (Destruction by neurolytic agent,

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<sup>11</sup> Id. at 85.

<sup>12</sup> Id. at 99.

<sup>13</sup> Id. at 102.

<sup>14</sup> Id. at 104.

<sup>15</sup> Id. at 112.

intercostal nerve). This decision was based on an AMA RUC review that found that this item no longer is typical for these services.<sup>16</sup>

Referral of Existing CPT Codes for RUC Review: As part of CMS's review of high-cost supplies, the agency concluded that most high-cost supplies could be used in the procedures for which they currently are direct PE inputs. One high-cost supply, however, (fiducial screws, CMS Supply Code SD073) is included as a direct PE input for two CPT codes, specifically, 77301 (Intensity modulated radiotherapy plan) and 77011 (Computed tomography guidance for stereotactic localization), yet CMS believes fiducial screws would not be used in CPT 77011 where the most common clinical scenario is the treatment of prostate cancer. Accordingly, CMS requested in the Proposed Rule that the AMA RUC review these CPT codes with respect to the inclusion of fiducial screws in their PE, and to furnish updated pricing information should the AMA RUC continue to recommend the screws as a PE input.<sup>17</sup> In response, the AMA RUC recommended that CMS remove the fiducial screws as a direct input from both CPT codes 77301 and 77011; CMS decided to implement this recommendation, subject to public comment on the Final Rule with comment period.<sup>18</sup>

Updating Equipment and Supply Price Inputs for Existing Codes: In the past, CMS periodically has received requests to change the PE price inputs for supplies and equipment in the PE database and has considered them on an *ad hoc* basis. In the Final Rule, the agency finalized its proposal to establish an annual process to update equipment and supply price inputs. Specifically, CMS will accept requests on an ongoing basis, but requests must be received no later than December 31 to be considered for inclusion in the next proposed rule. The Final Rule outlines what must be included in the request as well as parameters for including invoices. In the CY 2012 PFS proposed rule, CMS will present a review of any timely requests received by the agency to update supply price inputs or equipment price or useful life inputs.<sup>19</sup>

### Malpractice RVUs

As proposed, CMS will continue its current approach for determining malpractice RVUs for new and revised codes that become effective before the next five-year review and update. This approach involves crosswalking the new and revised codes to the RVUs of similar source codes and adjusting for differences in work (or, if greater, the clinical labor portion of the fully implemented PE RVUs), between the source codes and the new and revised codes. The CY 2011 malpractice RVUs for new and revised codes are being adopted as interim final rules in the CY 2011 PFS final rule with comment period, where they will be subject to public comment. They will then be finalized in the CY 2012 PFS final rule with comment period.<sup>20</sup>

### Potentially Misvalued Codes

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<sup>16</sup> Id. at 114.

<sup>17</sup> Id. at 118.

<sup>18</sup> Id. at 120.

<sup>19</sup> Id.

<sup>20</sup> Id. at 131.

Section 3134 of PPACA requires the Secretary to periodically identify potentially misvalued services in seven categories, including: codes and families of codes for which there has been the fastest growth; codes or families of codes that have experienced substantial changes in practice expenses; codes that are recently established for new technologies or services; multiple codes that are frequently billed in conjunction with furnishing a single service; codes with low relative values, particularly those often billed multiple times for a single treatment; codes which have not been subject to review since the implementation of the RBRVS (the so-called ‘Harvard-valued codes’); and other codes determined appropriate by the Secretary.

The Final Rule discusses the actions already taken by CMS in conjunction with the AMA RUC to identify potentially misvalued codes in all seven categories and sets forth five categories of codes that may be misvalued:

- Codes on the multi-specialty points of comparison list;
- Codes with low work RVUs (less than or equal to 0.5) that are commonly billed in multiple units (at least 5) per single encounter;
- Codes with a high volume based on claims data and low work RVUs (less than or equal to 0.25);
- Codes with site-of-service anomalies (i.e., the site of service has changed since the original valuation of the code); and
- Codes that qualify as “23-hour stay” outpatient services.

Section 3134 of PPACA also requires the Secretary of HHS to establish a formal process to validate RVUs under the PFS. The Final Rule articulates that CMS already does assess the AMA RUC-recommended work in this area, but that CMS proposes to adopt a more extensive validation process of RVUs in the future. In the Proposed Rule, CMS solicited comments on possible approaches and methodologies for the validation process, in particular to validate physician time and intensity.<sup>21</sup> CMS will discuss this validation process further in a future PFS rule once the agency has considered the issue, the comments received, and additional input from stakeholders. Any proposals made will be subject to public comment. In addition, as proposed, CMS will adopt specific methodologies to analyze codes with site-of-service anomalies as well as “23-hour stay” codes.<sup>22</sup>

### Expanding the MPPR Policy

Section 3134 of PPACA requires the Secretary to identify potentially misvalued codes by examining multiple codes that are frequently billed in conjunction with furnishing a single service, and review and make appropriate adjustments to their relative values. To begin implementation of this provision, CMS will adopt a limited expansion of the current imaging MPPR policy for CY 2011. Commenters, excluding MedPAC, uniformly opposed the expansion of the MPPR across families of imaging services, and many commenters opposed applying the MPPR to non-contiguous body parts. However, CMS believes that it would be “unnecessarily complex” to continue to refer to separate families of imaging services. CMS also believes that

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<sup>21</sup> Id. at 154.

<sup>22</sup> Id. at 183.

there would be some efficiencies when multiple imaging services of different modalities are provided to the same patient on the same day. The agency also notes that “the more general proposed policy would provide a streamlined basis for our further consideration of other possible expansions of an MPPR policy to the TC and/or PC of imaging procedures or other diagnostic tests in the future.”<sup>23</sup>

Effective January 1, 2007, CMS adopted an MPPR of 25 percent for the technical component (TC) of certain diagnostic imaging procedures, applied to the second and subsequent services when more than one service is furnished using the same imaging modality on a contiguous body area in a single session. Section 3135 of PPACA also increases the imaging MPPR from 25 percent to 50 percent, further reducing the reimbursement rate for the lower-priced procedure when more than one imaging service is provided on contiguous body parts in a single session. In the Final Rule, CMS finalized its proposal to extend the MPPR policy even further to multiple imaging services provided not only within the same family of codes, but across such families, and to add four additional CT CPT codes (75571, 75572, 75573, and 75574) to the policy. This change, if implemented, would reduce payment for 20 percent more services than the current MPPR policy under the PFS. Increasing the MPPR to 50 percent is not included in the budget neutrality adjustment, but extending the MPPR across families and adding the four additional CPT codes is included.<sup>24</sup>

The effect of the PE RVUs set forth in the Final Rule and the MPPR changes on physicians involved in cancer care will be:<sup>25</sup>

Specialty	Impact of PE RVU Changes	
	Full	Transitional
Hematology/Oncology	-4%	-2%
Radiation Oncology	-9%	-3%
Radiology	-12%	-7%

\* Does not include the impact of published reduction in the conversion factor.

**High Cost Supplies:** “MedPAC and the AMA RUC have long recommended that CMS establish a frequent price update process for high-cost supplies that are direct PE inputs in the PE database for services paid under the PFS”<sup>26</sup> to avoid the misvaluation of established services under the PFS. In the Proposed Rule, CMS identified 62 unique supplies with prices of \$150 or more. CMS requested comments both in terms of this list and with respect to a proposed, refined process for regularly updating the prices for high-cost supplies under the PFS.

Specifically, CMS proposed that this process would occur every two years, beginning as soon as CY 2013, and that the process would entail basing high-cost supply price inputs on the publicly available price listed on the GSA medical supply schedule or, if a supply price were not publicly available on the GSA medical supply schedule, based on the relationship between GSA prices at that time and the existing PE data price for similar supplies (currently an average 23

<sup>23</sup> Id. at 201.

<sup>24</sup> Id. at 183.

<sup>25</sup> Id. at 1428.

<sup>26</sup> Id. at 240.

percent reduction). CMS notes that because “the GSA medical supply schedule is a source for pricing information that is public and transparent and reflects the best government contract price for a product, we believe it is desirable resource . . . to use in a refined process for updating high-cost supplies.”<sup>27</sup> ACCC, like many commenters, expressed concern that the GSA is not representative of the prices available to physicians treating Medicare providers. CMS stated in the Final Rule that the agency does not agree that the usefulness of the GSA is undermined solely because large government buyers benefit from some exclusive discounts. Nonetheless, CMS noted the agency’s interest in receiving further public comments that substantiate the claims that medical supplies on the GSA schedule are not representative of actual prices paid by typical practitioners caring for Medicare patients. CMS also invited suggestions for alternative approaches to updating high-cost supply prices, specifically those that would result in a predictable, public, and transparent methodology that would ensure that the prices in the PE database reflect typical market prices.

### Rebasing and Revising the Medicare Economic Index (MEI)

The MEI is a “fixed-weight input price index, with an adjustment for the change in economy-wide, private nonfarm business multifactor productivity.”<sup>28</sup> The MEI is composed of two broad categories: (1) the physician’s own time; and (2) physician’s PE. As proposed, CMS will rebase and revise the MEI and incorporate it into the CY 2011 PFS update. “Rebasing refers to moving the base year for the structure of costs of the input price index, while revising relates to other types of changes such as changing data sources, cost categories, or price proxies used in the price index.”<sup>29</sup> CMS moved the base year to 2006 from 2000. CMS selected 2006 as the base year both because it was the most recent year for which data were available and because CMS believes that the 2006 data provides a representative distribution of physicians’ compensation and PEs.

In addition to the rebase, as proposed, CMS made several revisions to the MEI in the Final Rule. First, CMS removed all costs related to drug expenses from the MEI because drugs are not paid for under the PFS and are not included in the definition of “physicians’ services.” Second, CMS also removed costs associated with separately billable supplies. Third, CMS proposed to revise the cost categories in the MEI by expanding the Office Expense category into nine detailed categories with associated price proxies, however, in response to comments received, CMS instead added an additional category to disaggregate the costs under the broader “Office Expenses” cost category, for a total of ten such categories. These categories and their weights were used to revise the cost categories in the MEI, primarily derived from data collected in the 2006 AMA PPIS for self-employed physicians and selected self-employed non-Medical Doctor (non-MD) specialties.

According to CMS, the 2006-based MEI annual percent changes differ from the 2000-based MEI annual percent changes by 0.0 to 0.8 percentage points, the majority of these differences being attributable to the lower benefit cost weight, as measured by the 2006 AMA data, and the exclusion of the drug cost weight. As a result of the rebasing and revision, as

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<sup>27</sup> Id. at 251.

<sup>28</sup> Id. at 305.

<sup>29</sup> Id. at 306.

illustrated by the following chart, the relative weight given to practice expenses and professional liability insurance will increase and the relative weight given to physician’s own compensation will decrease.<sup>30</sup>

	<b>CY 2006 Weight</b>	<b>CY 2000 Weight</b>
Physician Compensation (Own Time)	48.266%	52.466%
Practice Expenses (Less PLI)	47.439%	43.669%
Professional Liability Insurance (PLI)	4.295%	3.865%

To implement these changes, CMS will maintain current work RVUs and to increase the PE RVUs by an adjustment factor of 1.181 percent (proposed 1.168 percent) and the malpractice RVUs by an adjustment factor of 1.358 percent (proposed 1.413 percent). In addition, to ensure that the expenditures do not change to an extent prohibited by law, CMS will make an adjustment of 0.9181 (proposed 0.921) to the CY 2011 conversion factor. This adjustment is included in the published conversion factor of \$25.517. The annual percent change for the current MEI for CY 2011 is forecasted to be 0.3 percent, and the revised and rebased MEI for CY 2011 is forecasted to be 0.4 percent.<sup>31</sup> The revised and rebased MEI for CY 2011 was forecasted to be 0.3 percent in the proposed rule. According to CMS, the 0.1 percent change is primarily related to the incorporation of more recent historical data for non-farm business multifactor productivity since the publication of the Proposed Rule.

The effect of the MEI rebasing and revising proposals on physicians involved in cancer care would be:<sup>32</sup>

Specialty	Impact of MEI Rebasing
Hematology/Oncology	2%
Radiation Oncology	4%
Radiology	-1%

**Part B Drug Payment: Average Sales Price (ASP) Issues**

ASP-Based Payment for Biosimilar Biological Products: The Final Rule conforms regulations to the reimbursement formula enacted under PPACA for biosimilar biological products. The reimbursement rate for biosimilars will be equal to (1) the weighted average ASP for all national drug codes (NDCs) assigned to the biosimilar biological product, plus (2) six percent of the weighted average sales price (ASPs), or wholesale acquisition costs (WACs), if

<sup>30</sup> Id. at 330.

<sup>31</sup> Id. at 332.

<sup>32</sup> Id. at 1428-29.

lower, for all NDCs assigned to the reference product. The statute defines the term “biosimilar biological product” as “a biological products approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biological product licensed under section 351 of the Public Health Service Act,” and the “reference biological product” as “the biological product licensed under such section 351 of the PHS Act that is referred to in the application of the biosimilar biological product.”<sup>33</sup>

CMS anticipates that as biosimilar biological products are approved, CMS will receive ASP sales data through the ASP data submission process and publish national payment amounts in the same manner as for other drugs and biologicals. Until such data are received, the payment will be determined based on the WAC or the methodologies in effect on November 1, 2003. If no manufacturer data is collected, prices will be determined by local contractors using any available pricing information, including provider invoices.<sup>34</sup>

Carry-Over ASPs: To address the circumstance where a manufacturer has failed to report ASP data for one or more NDCs in a given billing and payment code, and where CMS has made an effort to obtain the necessary ASP data before the ASP payment limit publication deadline but has been unsuccessful, as proposed, CMS will “carry-over,” or use the prior quarter ASP data for those NDCs that lack current quarter ASP data, with the carry-over ASPs adjusted by the weighted average change in the ASPs for the NDCs that were reported for the prior and current quarter. The Final Rule specifies that, as proposed, CMS will use carry-over ASPs only where it expects that the missing ASP (or WAC data) would cause significant changes or fluctuations in the ASP payment limits, defined as a change that is 10 percent or greater. In response to comments on the Proposed Rule, CMS will not apply this policy to single source drugs and biologicals. In addition, this policy will not be applied to multiple source NDCs that have zero sales or that have been permanently discontinued. The Final Rule makes clear that this change would not affect CMS or Office of Inspector General (OIG) authority to assess civil monetary penalties associated with untimely or false ASP reporting.<sup>35</sup>

Partial Quarter ASP Data: The Final Rule clarifies CMS's policy with regard to how ASP data are used in the calculation of ASP payment limits during the first quarter of sales for single source and multiple source drugs, when typically there is not a full quarter of data. Specifically, CMS explains that it has been the agency’s “policy to price new single source drugs at WAC for the first quarter (unless the date of first sale is on the first day of the quarter), and to add new NDCs for multisource drugs and product line expansions of single source drugs to the ASP calculation for a quarter as soon as these products are reported.”<sup>36</sup>

Determining the Payment Amount for Drugs and Biologicals Which Include Intentional Overfill: The Final Rule addresses the treatment of overfill in the ASP calculation for a given NDC. Specifically, CMS states that overfill volume contained in a given NDC-11 should not be counted in the ASP calculation for that NDC, and instead the ASP should be determined based on the product’s approved labeling. The Final Rule also states that, because CMS understands

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<sup>33</sup> Id. at 715.

<sup>34</sup> Id. at 716.

<sup>35</sup> Id. at 949-50.

<sup>36</sup> Id. at 958.

that any overfill included in a product is provided free of charge to the purchasing provider, “providers may not bill Medicare for overfill harvested from containers, including overfill amounts pooled from more than one container, because that overfill does not represent a cost to the provider. Claims for drugs and biologicals that do not represent a cost to the provider are not reimbursable, and providers who submit such claims may be subject to scrutiny and follow up action by CMS, its contractors, and OIG.”<sup>37</sup> CMS also states that it does not intend to track overfill amounts for injectable drugs.

WAMP/AMP Substitution for ASP: The Final Rule includes specific provisions regarding the appropriate circumstances for substituting the lesser of WAMP or 103 percent of AMP for the ASP-based payment limit as well as the timing for doing so. The Final Rule continues the five percent threshold for comparing WAMP/AMP to ASP, and CMS notes that the data was too limited to support an adjustment to the current applicable threshold percentage. CMS provides additional information regarding the potential substitution of AMP for ASP. CMS also proposed to substitute 103 percent of AMP for the ASP-based payment limit to remain in effect for one quarter where:

- (1) ASP exceeds AMP by five percent either in the two consecutive quarters immediately prior to the current pricing quarter, or three of the previous four quarters immediately prior to the current quarter;
- (2) the AMP and ASP comparisons are based on the same set of NDCs for a billing code; and
- (3) 103 percent of AMP is less than the 106 percent of ASP during the quarter to which the AMP would be applied.<sup>38</sup>

However, the Proposed Rule acknowledged that CMS will not implement this price substitution policy, however, until the preliminary injunction in *National Association of Chain Drug Stores et al. v. Health and Human Services* that does not permit it to publicly disclose AMP data is modified.<sup>39</sup> As this injunction is still in effect, CMS did not finalize this proposal in the Final Rule.

#### Clinical Laboratory Fee Schedule: Signature on Requisition

The Final Rule acknowledges the existing confusion surrounding the implementation of CMS’s 2001 policy regarding signatures on requisitions for clinical diagnostic laboratory tests. In an attempt to mitigate this confusion, CMS finalized its proposal that a physician or nonphysician practitioner (NPP) must sign a requisition for clinical diagnostic laboratory tests paid on the basis of the clinical laboratory fee schedule (CLFS). This is a change of policy for CMS, which, in 2010, had proposed that physicians and NPPs were not required to sign such requisitions, but that they must sign written orders. This new policy aims to avoid the confusion

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<sup>37</sup> Id. at 965.

<sup>38</sup> Id. at 981.

<sup>39</sup> Id. at 982-83.

and uncertainty over whether a particular document is a requisition or an order, whether the type of test being ordered requires a signature, or which payment system does or does not require a physician or NPP signature.<sup>40</sup>

### Improvements to the PQRI

The PQRI is a voluntary reporting program, first implemented in 2007, that provides an incentive payment to identified [eligible professionals] (EPs) who satisfactorily report data on quality measures for covered professional services furnished during a specified reporting period.<sup>41</sup> In the Final Rule, CMS renames the PQRI, the “Physician Quality Reporting System” (PQRS) to reflect its transition from a temporary initiative to a permanent quality reporting program. For CY 2011, CMS had proposed to add 20 new measures and one new measures group, however, in the Final Rule, CMS adopted only 16 of these proposed measures and the new measures group. In addition, as proposed, CMS will largely maintain their previous slate of measures and measure groups. In addition, to facilitate reporting by EPs, CMS will add 20 of the 22 proposed measures to the list of measures that can be reported through the electronic health records system – although none of these measures is specifically related to cancer care – and will reduce the reporting sample requirements for the reporting of individual measures from 80 percent to 50 percent for claims-based reporting. CMS will also create a new Group Practice Reporting Option (GPRO) that will allow participation by group practices with fewer than 200 EPs. In addition, PPACA makes a number of changes to the PQRI.

Incentive Payments: Prior to the enactment of PPACA, incentive payments were authorized only through 2010. Section 3002(a) of PPACA authorizes a 1.0 percent incentive payment for 2011 and a 0.5 percent incentive payment for 2012 through 2014 for qualified EPs who satisfactorily submit PQRS quality measures data. Under this provision, EPs that satisfactorily report will receive incentive payments in CY 2011 at the individual tax identification number (TIN) / National Provider Identifier (NPI) number; practices that successfully report will be paid upon qualified charges for the group practice TIN.<sup>42</sup>

Penalty Payments: Beginning in 2015, an incentive payment adjustment will be implemented for EPs who do not satisfactorily report quality measures under the PQRI. Such individuals will be subject to a 1.5 percent penalty for 2015 and a 2 percent penalty in 2016 and subsequent years. This penalty will be addressed by CMS in future notice-and-comment rulemaking.<sup>43</sup>

Timely Feedback: Section 3002(e) of PPACA requires the Secretary to provide timely feedback to EPs on their performance with respect to their performance in satisfactorily submitting data on quality measures. To do so, CMS finalized its proposal to issue feedback reports at or around the time of the issuance of the incentive payments, consistent with CMS’s current practice, and also proposes to provide interim feedback reports for those EPs reporting

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<sup>40</sup> Id. at 1035.

<sup>41</sup> Id. at 1053.

<sup>42</sup> Id. at 1062.

<sup>43</sup> Id. at 1208.

PQRI measures groups through the claims-based reporting mechanism.<sup>44</sup> Although CMS proposed to implement this policy for the 2011 incentive payments, in the Final Rule, CMS noted that the agency did not believe that it would have the technical capability needed to issue interim feedback reports until the 2012 incentive payments, at which time CMS also anticipates being able to provide additional interim feedback reports.

Informal Appeals Process: Section 3002(f)(2) of PPACA requires the Secretary to establish and have in place an informal appeals process by January 1, 2011, whereby EPs may seek review of a determination that the EP did not satisfactorily submit data on quality measures for purposes of qualifying for a PQRI incentive payment. To implement this provision, CMS will base this informal process on the agency's current inquiry process and will adopt the following procedure:

- An EP electing to use the informal process must request an informal review within 90 days of the release of his or her feedback report by notifying the Quality Net Help Desk. Although there will not be an informal hearing or evidence submission process, an EP may submit information to assist the review.
- CMS provides the EP with a response to his or her request for an informal review within 60 days of receiving the original request, including a written response. Where CMS finds that the EP did satisfactorily report, CMS will include the applicable incentive payment.
- Decisions of the informal review process are to be final.

CMS will post further information regarding the operational aspects of the informal review process on the CMS PQRI website by December 31, 2011.<sup>45</sup>

Maintenance of Certification Programs: Section 10327(a) of PPACA provides that, for years 2011 through 2014, the applicable quality percent under the PQRI for EPs satisfactorily reporting PQRI quality measures data may also be increased by 0.5 percent if the EP satisfactorily participates in a Maintenance of Certification Program (MOCP). To qualify for the incentive payments on this basis, the EP must (1) satisfactorily report data on quality measure for a year, (2) have such data submitted on their behalf through a MOCP, and (3) participate in an MOCP practice assessment more frequently than is required merely to maintain board certification status. In the Final Rule, CMS establishes that a MOCP that wishes to enable their members to be eligible for an additional PQRI incentive payment on this basis must go through a self-nomination process by January 31, 2011 and meet the requirements for registries articulated in the Proposed Rule with respect to the PQRI program.<sup>46</sup> In addition, for years after 2014, the Secretary may incorporate participation in an MOCP into the composite of measures of quality of care furnished pursuant to the physician fee schedule payment modifier.<sup>47</sup>

Physician Compare Website: Section 10331 of PPACA "requires the Secretary to develop a Physician Compare Internet Web site by January 1, 2011, on which information on physicians enrolled in the Medicare program and other" EPs who participate in the PQRI

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<sup>44</sup> Id. at 1235.

<sup>45</sup> Id. at 1244-49.

<sup>46</sup> Id. at 1215, 1231.

<sup>47</sup> Id. at 1210, 1231.

program would be posted.<sup>48</sup> CMS intends to post the names of eligible professionals and group practices who: (1) submit data on the 2011 PQRI quality measures for; (2) meet specified satisfactory reporting criteria; and (3) qualify to earn a PQRI incentive payment. CMS also plans to develop the Physician Compare Web site by January 1, 2011.

Quality Measures & Meaningful Use: Section 3002(d) of PPACA requires the Secretary, not later than January 1, 2012, to develop a plan to integrate reporting on quality measures relating to the meaningful use of electronic health records (EHRs).<sup>49</sup> To do so, CMS finalized its proposal to include many of the core clinical quality measures articulated under the American Recovery and Reinvestment Act of 2009 (ARRA) in the PQRI program. CMS further proposed to select such measures to meet the requirements of planning the integration of PQRI and EHR reporting.<sup>50</sup>

### Physician Feedback

The Medicare Improvements for Patients and Providers Act (MIPPA) required CMS to establish a Physician Resource Use Measurement and Reporting (RUR) Program to provide confidential reports to physicians regarding the resources used to furnish care to Medicare beneficiaries. This provision also permitted CMS to include information on the quality of care in such reports. CMS already has implemented Phase I of this RUR Program by reporting resource and quality measures to individual physicians in 12 geographic areas. CMS intends to distribute reports in Phase II of this program in fall of 2010. CMS will base these Phase II reports on claims-based measures developed by CMS as part of the Generating Medicare Physician Quality Performance Measurement Results (GEM) project, rather than PQRS data.<sup>51</sup> In addition, CMS intends 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.

Section 3003 of PPACA continues the confidential feedback program and requires the Secretary, beginning in 2012, to provide reports to physicians that compare their patterns of resource use to other physicians. This section also requires the Secretary to develop a Medicare-specific episode grouper by January 1, 2012. In the interim, CMS finalized its proposal to discontinue use of its current episode grouper and to provide overall per capita cost information, as well as per capita cost information for those beneficiaries with five common chronic diseases: diabetes, congestive heart failure, coronary artery disease, chronic obstructive pulmonary disease, and prostate cancer. “This information will not be limited 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 the care received by the subset of attributed beneficiaries with that disease.”<sup>52</sup>

In the Proposed Rule, CMS sought comments on the following aspects of the RUR Program:

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<sup>48</sup> Id. at 1196.

<sup>49</sup> Id. at 1232.

<sup>50</sup> Id. at 1235.

<sup>51</sup> This report is available at: [www.cms.gov/GEM](http://www.cms.gov/GEM).

<sup>52</sup> Id. at 660.

- The appropriate method for risk-adjusting cost data for use in reporting per capita and episode-based cost information.<sup>53</sup>
- Methodologies for attributing care to specific physicians, including the “multiple-proportional” and “plurality-minimum” methodologies that have already been used in the program.<sup>54</sup>
- The most appropriate and relevant peer groups for comparison between physicians, including the appropriate minimum case sizes and minimum peer group sizes.<sup>55</sup>

Based on comments received, CMS decided to employ the same hierarchical condition category (HCC) model for its risk adjustment for per capita cost measures in Phase II of the RUR Program.<sup>56</sup> CMS also stated that the agency “plan[s] 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.”<sup>57</sup> Finally, CMS stated that the agency “will use the peer group and minimum case size of 30” for comparison between physicians, as outlined in the Proposed Rule.<sup>58</sup>

### Value-Based Payment Modifier

Section 3007 of PPACA requires the Secretary to apply a separate, budget-neutral payment modifier to the PFS, to be phased in from January 1, 2015, through January 1, 2017. This payment modifier will provide for differential payment under the PFS to a physician or group of physicians based on the quality of the care they provide to Medicare beneficiaries relative to cost. CMS is required to publish the cost and quality measures the agency intends to use in determining the payment modifier by January 1, 2012. Such measures may include successful completion of an MOCP and MOCP practice assessment, discussed above. In anticipation of implementing these provisions, CMS intends to perform extensive data analysis and research and to seek stakeholder input on issues related to cost and quality measures so the agency can be prepared to publish the measures it intends to use for the payment modifier.<sup>59</sup>

### Incentives for Electronic Prescribing (eRx):

The eRx Incentive Program—a program separate and in addition to incentives earned under the PQRI program—promotes the use of electronic prescribing by authorizing incentive payments to EPs<sup>60</sup> or group practices who are “successful electronic prescribers.” CMS’s intention with respect to this program in 2011 (the third year of the program) is to continue to

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<sup>53</sup> Id. at 668.

<sup>54</sup> Id. at 670.

<sup>55</sup> Id. at 673.

<sup>56</sup> Id. at 669.

<sup>57</sup> Id. at 672.

<sup>58</sup> Id. at 674.

<sup>59</sup> Id. at 666.

<sup>60</sup> An EP for purposes of this provision is defined in the same manner as under the PQRI program, but is further restricted to those providers with prescribing authority. Detailed information about eligible providers can be found at: <http://www.cms.gov/ERXIncentive>.

encourage significant expansion of the use of electronic prescribing by authorizing a combination of financial incentives and payment adjustments. Providers that successfully participate in this program in 2011 will receive a statutorily-determined incentive payment of 1.0 percent of the total estimated Medicare Part B fee schedule allowed charges for all covered professional services performed during the reporting period. One of the requirements of a qualified electronic prescribing system is that it allows EPs to “select medications, print prescriptions, electronically transmit prescriptions, and conduct alerts (written or acoustic signals to warn the prescriber of possible undesirable or unsafe situations including inappropriate dose or route of administration of a drug, drug-to-drug interactions, allergy concerns, or warnings and cautions.)”<sup>61</sup> Notably, CMS clarified in the Final Rule that this incentive payment is unavailable for EPs that receive incentive payments under the Medicare EHR Incentive Program. In addition, CMS finalized its proposed methodology to implement a statutorily-required penalty provision applicable to EPs who are not successful electronic prescribers beginning in 2012.<sup>62</sup>

### Implementation of PPACA

In addition to the various changes enacted by PPACA discussed above for which CMS has made proposals for implementation, there are a number of other provisions of PPACA discussed in the Proposed and Final Rules.

Extension of Payment for Technical Component of Certain Physician Pathology Services: In 2000, CMS issued a regulation stating that, “for physician pathology services furnished on or after January 1, 2001 by an independent laboratory, payment is made only to the hospital for the TC furnished to a hospital inpatient”<sup>63</sup> and not to the laboratory. The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) delayed the implementation of this policy, allowing independent laboratories to continue to bill Medicare for the TC of physician pathology services for fee-for-service Medicare beneficiaries who are inpatients or outpatients of a covered hospital. This delay was further extended by several subsequent legislative acts, including the PPACA, which extends this payment through CY 2010. Accordingly, CMS finalized its proposal to revise the applicable regulation to amend the effective date for its payment policy.<sup>64</sup>

Extension of Medicare Reasonable Costs Payments for Certain Clinical Diagnostic Laboratory Tests Furnished to Hospital Patients in Certain Rural Areas: The “MMA established a reasonable cost payment for outpatient clinical diagnostic laboratory tests furnished by hospitals with fewer than 50 beds that are located in qualified rural area for cost reporting periods beginning during the 2-year period beginning July 1, 2004.”<sup>65</sup> This reasonable cost payment was extended by various subsequent pieces of legislation through June 29, 2009. PPACA reinstates reasonable cost payment for clinical diagnostic laboratory tests performed on or after July 1, 2010, through June 30, 2011. This provision may affect services performed as late as June 29, 2012, because this is the date those cost reports will close.

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<sup>61</sup> Final Rule, Display Copy at 1269.

<sup>62</sup> Id. at 1287.

<sup>63</sup> Id. at 682.

<sup>64</sup> Id. at 683

<sup>65</sup> Id. at 699.

Removal of Barriers to Preventive Services in Medicare: Section 4104(b)(4) of PPACA requires Medicare to pay 100 percent Medicare payment (as opposed to 80 percent, with 20 percent beneficiary cost-sharing) for preventive services recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B for any indication or population that are appropriate for the individual. In addition, Sections 4103(c)(1) and 4104(c) waive the applicable coinsurance and deductible, respectively, for preventive services under Medicare to which the USPSTF has given a grade of A or B, regardless of where the service is furnished. These services include screening mammography, screening pap smear and screening pelvic exam, and certain prostate cancer and colorectal screening tests that have received a sufficient grade from the USPSTF.<sup>66</sup> To implement this provision, CMS will update the regulation that lists services for which expenses incurred are not subject to the Part B annual deductible to include HCPCS codes determined to be “preventive services.” The Final Rule includes a list of these HCPCS codes.<sup>67</sup>

Although certain prostate and colorectal cancer screening tests have not received the requisite grade of A or B from the USPSTF,<sup>68</sup> these tests already are exempt from coinsurance and deductibles under section 1833 of the Social Security Act (SSA), which waives the deductible and coinsurance for clinical laboratory tests whether or not the test meets the USPSTF grading criteria.<sup>69</sup> In addition, section 4104(c) of the PPACA amends the SSA to waive the Part B deductible for colorectal screening tests that become diagnostic, as well as other procedures furnished in connection with, as a result of, and in the same clinical encounter as a screening test. As proposed, all clinical services furnished on the same date as a planned screening colonoscopy, planned flexible sigmoidoscopy, or barium enema will be considered to be furnished in connection with, as a result of, and in the same clinical encounter as the screening test. CMS also finalized its proposal to implement this provision by creating a HCPCS modifier to append to the diagnostic procedure code that is reported instead of these screening codes when the screening test becomes a diagnostic service. CMS notes that the claims processing system could respond to the modifier by waiving the deductible for all surgical service on the same date as the diagnostic test. Notably, the beneficiary still would be required to pay coinsurance for these visits.<sup>70</sup> The Office of the Actuary (OACT) estimates the impact on a fiscal year cash basis to be \$110 million for FY 2010.<sup>71</sup>

Incentive Payment for Major Surgical Procedures Furnished in HPSAs: Section 5501(b) of PPACA provides a 10 percent incentive payment in the case of major surgical procedures

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<sup>66</sup> The USPSTF has given a grade of A or B to screening colonoscopy, screening flexible sigmoidoscopy, and fecal occult blood screening tests.

<sup>67</sup> See Final Rule, Display Copy at 818.

<sup>68</sup> Digital rectal examinations furnished as a prostate cancer screening service and barium enema furnished as a colorectal cancer screening service are not recommended by the USPSTF with a grade of A or B for any indication or population.

<sup>69</sup> For example, the deductible and coinsurance for HCPCS code G0103 (Prostate cancer screening; prostate specific antigen test (PSA)) will continue to be waived under section 1833 of the SSA, even though PSA testing does not have a grade of A or B from the USPSTF.

<sup>70</sup> Final Rule, Display Copy at 831-32.

<sup>71</sup> *Id.* at 832.

furnished by a general surgeon on or after January 1, 2011, and before January 1, 2016, in an area designated as a HPSA. For purposes of this provision, a general surgeon is defined as a doctor of medicine or osteopathy, dental surgeon, doctor of podiatric medicine, or doctor of optometry, who has designated a CMS specialty code of 02-General Surgery as his or her primary specialty code in the Medicare physician enrollment process. Major surgical procedures are defined as surgical procedures for which a 10-day or 90-day global period is used for payment under the MPFS.

CMS has identified approximately 4,300 surgical procedure codes that would have met the surgical procedure code for the incentive payment had it been applicable in CY 2010. As proposed, these payments will be calculated by the Medicare payment contractors and be made on a quarterly basis. If the claim is submitted on behalf of the physician by a critical access hospital (CAH), the rendering physician's NPI must be included in the line item for the major surgical procedure in order to receive the payment. CMS also finalized its proposal to use the same HPSA list applicable to primary care bonus payments for purposes of this provision<sup>72</sup> and, adopted a modified version of its proposal to create a modifier for HPSAs designated as of December 31 of the previous year that are not on the list. Finally, CMS modified its proposal that payment for professional services to the CAH at 115 percent of the MPFS amount under the optional payment method would not take into account these payments. CMS does not anticipate that surgeons will change their specialty designation to receive these payments, but will consider making future revisions to eliminate such outcome if CMS finds that physicians are doing so.<sup>73</sup>

Disclosure Requirements for In-Office Ancillary Services: Under the physician self-referral law, a physician is prohibited from billing Medicare for referrals for certain designated health services (DHS) payable by Medicare to any entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies. One such exception is the "In-office Ancillary Services" exception that permits a physician in a solo or group practice to order and provide DHS in the office of the physician of the group practice – subject to certain limitations – provided that specific criteria are met regarding who furnishes the service, where the service is performed, and who bills for the service. Section 6003 of PPACA creates a new disclosure requirement that must be met in order to qualify for the in-office ancillary services exception. Specifically, with respect to referrals for MRI, CT, PET, clinical laboratory services, and other DHS specified by section 1877(h)(6)(D) of the SSA determined appropriate by the Secretary, CMS is required to promulgate a requirement that the referring physician inform a patient in writing at the time of the referral that the patient may obtain the service from a person other than the referring physician and to provide the patient with a list of alternative providers that furnish the relevant services in the area in which the patient resides. As proposed, CMS will not expand the disclosure requirement beyond advanced radiology and imaging services. The regulation implementing this provision will be effective on January 1, 2011.<sup>74</sup>

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<sup>72</sup> This list of health professional shortage areas is available at:  
[http://www.cms.gov/hpsapsaphysicianbonuses/01\\_overview.asp](http://www.cms.gov/hpsapsaphysicianbonuses/01_overview.asp).

<sup>73</sup> Final Rule, Display Copy at 864.

<sup>74</sup> Id. at 874.

CMS requires that the notice be “written in a manner sufficient to be reasonably understood by all patients and should include for each supplier on the list, at a minimum, the supplier’s name, address, and telephone number.”<sup>75</sup> In addition, to reduce the administrative burden on physicians of providing a list of providers “in the area in which [the patient] resides,” CMS is finalizing its proposal that the suppliers included in this notice should be located within a 25-mile radius of the physician’s office location at the time of the referral, whether the office is located in a rural or urban area. CMS will also require that this list include at least 5 (proposed 10) other suppliers, unless there are fewer than 5 (proposed 10) suppliers within the 25-mile radius, and that the list include additional information regarding each supplier, including contact information. CMS did not finalize its proposed requirement that the distance of the supplier from the physician’s office also be included in this list. CMS also did not finalize its proposed requirement that physicians document that the disclosure requirement has been satisfied. CMS is not creating an exception from this requirement for emergency or time-sensitive procedures.<sup>76</sup>

CMS estimates that 71,000 Medicare-enrolled physicians would have to comply with this new requirement, which represents 20 percent of primary care and medical specialty physicians enrolled in Medicare Part B.

Maximum Period for Submission of Medicare Claims Reduced to Not More than 12 Months: Prior to the enactment of PPACA, Medicare providers had three years after the date of service to file a claim. Section 6404 of PPACA provides that, for all services furnished on or after January 1, 2010, claims must be filed within one calendar year after the date of service. In addition, for any services furnished before January 1, 2010, claims must be submitted by December 31, 2010. To implement this provision, CMS has amended the applicable regulation accordingly.

Section 6404 gives the Secretary authority to create exceptions to the one-year timely filing period. In addition to the existing exception to the timely filing requirement due to error or misrepresentation by CMS, its contractors or agents, CMS will create two additional exceptions. First, CMS is creating an exception for those situations where a beneficiary becomes retroactively entitled to Medicare benefits on or before the date of service, but was not entitled at the time the services were furnished, in which case the time to file a claim will be extended through the last day of the sixth calendar month following the month in which the beneficiary and/or provider/supplier received notification of Medicare entitlement. Second, CMS is creating an exception for dually-eligible beneficiaries where: at the time of service, the beneficiary was not entitled to Medicare, the beneficiary subsequently received retroactive Medicare benefits to or before the date of service, and a state Medicaid agency recovered the Medicare payment for the furnished service from the provider or supplier 6 months (proposed 11 months) or more after the date of service, leaving the provider responsible to bill Medicare for the service. CMS also added an additional exception in the Final Rule for retroactive disenrollment from Medicare Advantage Plans or Program for All-inclusive Care for the Elderly (“PACE”) provider organizations. With respect to the exception due to error or misrepresentation by CMS, its contractors or agents, CMS will not grant an extension of time beyond four years after the date of service, as proposed. CMS is not interpreting the term “date of service” in the Final Rule, but

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<sup>75</sup> *Id.* at 1499.

<sup>76</sup> Final Rule, Display Copy at 889.

instead has issued sub-regulatory guidance with respect to this issue,<sup>77</sup> and has proposed to issue more such guidance in the future.<sup>78</sup>

According to CMS, the budgetary impact related to this provision is significant as future payment of claims for services incurred will now be made at an earlier date, which is reflected by the Part A and Part B payment amounts of \$60 million and \$50 million for FY 2011.<sup>79</sup>

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<sup>77</sup> Centers for Medicare & Medicaid Services, Change Request 6969 (May 7, 2010); Centers for Medicare & Medicaid Services, Change Request 7080 (July 30, 2010).

<sup>78</sup> Final Rule, Display Copy at 902.

<sup>79</sup> Id. at 1450.

**Comparison of 2010 and 2011 Physician Fee Schedule Payment Rates for Drug Administration Services**  
(calculated using the November 2010 conversion factor)

Code	Description	2010		2011		% Change 2010-2011	
		2010 Non-Facility	2010 Facility	2011 Non-Facility	2011 Facility	Non-Facility	Facility
96360	Hydration iv infusion, init	\$54.94	NA	\$61.95	NA	12.75%	NA
96361	Hydrate iv infusion, add-on	\$15.49	NA	\$16.96	NA	9.52%	NA
96365	Ther/proph/diag iv inf, init	\$67.48	NA	\$77.43	NA	14.75%	NA
96366	Ther/proph/dg iv inf, add-on	\$21.02	NA	\$23.60	NA	12.28%	NA
96367	Tx/proph/dg addl seq iv inf	\$32.82	NA	\$35.77	NA	8.99%	NA
96368	Ther/diag concurrent inf	\$19.54	NA	\$21.39	NA	9.43%	NA
96369	Sc ther infusion, up to 1 hr	\$148.50	NA	\$186.21	NA	25.31%	NA
96370	Sc ther infusion, addl hr	\$15.12	NA	\$16.59	NA	9.76%	NA
96371	Sc ther infusion, reset pump	\$76.70	NA	\$87.02	NA	13.46%	NA
96372	Ther/proph/diag inj, sc/im	\$21.76	NA	\$25.07	NA	15.25%	NA
96373	Ther/proph/diag inj, ia	\$18.44	NA	\$20.65	NA	12.00%	NA
96374	Ther/proph/diag inj, iv push	\$53.83	NA	\$60.84	NA	13.01%	NA
96375	Ther/proph/diag inj add-on	\$22.49	NA	\$24.70	NA	9.84%	NA
96401	Chemo, anti-neopl, sq/im	\$68.95	NA	\$79.28	NA	14.97%	NA
96402	Chemo hormon antineopl sq/im	\$35.77	NA	\$38.35	NA	7.22%	NA
96405	Chemo intralesional, up to 7	\$83.70	\$29.50	\$93.66	\$32.82	11.89%	11.25%
96406	Chemo intralesional over 7	\$116.52	\$43.51	\$128.69	\$47.93	10.44%	10.17%
96409	Chemo, iv push, sngl drug	\$109.51	NA	\$122.79	NA	12.12%	NA
96411	Chemo, iv push, addl drug	\$61.58	NA	\$68.95	NA	11.98%	NA
96413	Chemo, iv infusion, 1 hr	\$143.07	NA	\$159.66	NA	11.60%	NA
96415	Chemo, iv infusion, addl hr	\$30.97	NA	\$33.92	NA	9.52%	NA
96416	Chemo prolong infuse w/pump	\$156.71	NA	\$175.88	NA	12.24%	NA
96417	Chemo iv infus each addl seq	\$70.80	NA	\$78.91	NA	11.46%	NA
96420	Chemo, ia, push technique	\$105.83	NA	\$118.73	NA	12.20%	NA
96422	Chemo ia infusion up to 1 hr	\$169.98	NA	\$191.00	NA	12.36%	NA
96423	Chemo ia infuse each addl hr	\$77.06	NA	\$87.02	NA	12.92%	NA
96425	Chemotherapy, infusion method	\$170.72	NA	\$195.80	NA	14.69%	NA
96440	Chemotherapy, intracavitary	\$666.66	\$143.80	\$793.87	\$160.77	19.08%	11.79%
96445	Chemotherapy, intracavitary	\$283.55	\$120.57	\$192.86	\$23.23	-31.99%	-80.73%
96450	Chemotherapy, into CNS	\$202.43	\$88.13	\$216.44	\$92.92	6.92%	5.44%
96521	Refill/maint, portable pump	\$126.11	NA	\$144.91	NA	14.91%	NA
96522	Refill/maint pump/resvr syst	\$106.93	NA	\$120.94	NA	13.10%	NA
96523	Irrig drug delivery device	\$24.70	NA	\$27.65	NA	11.94%	NA
96542	Chemotherapy injection	\$128.69	\$44.62	\$138.27	\$47.57	7.45%	6.61%