On October 31, 2014 the Centers for Medicare and Medicaid Services (CMS) released Medicare’s CY 2015 Physician Fee Schedule (PFS) Final Rule as well as its CY 2015 Hospital Outpatient Prospective Payment System (OPPS) Final Rule. Despite the drastic cuts to reimbursement seen in recent years, the overall predicted impact of the PFS Final Rule on the pathology and laboratory community is neutral. Nonetheless, while there are several favorable policies finalized this year, by far the biggest upsets in both rules are derived from the Agency’s attempt to “mitigate overutilization incentives” via varying iterations of bundled payment billing schemes. The problem with these policies is twofold: CMS is overly aggressive with claiming efficiencies—oftentimes where there aren’t any—while conversely failing to accurately account for the aggregate costs of additional services being bundled.

Consolidation of Prostate Biopsy G-Codes into One G-Code

In this year’s PFS Final Rule, CMS finalized its proposals to consolidate the four existing prostate biopsy G-codes into one G-code (G0416 [Surgical pathology, gross and microscopic examination for prostate needle biopsies, any method; 10 to 20 specimens]), revise the G-code’s descriptor to define the service regardless of the number of specimens, and delete the remaining three G-codes (G0417–G0419). Accordingly, CMS stated its belief that the typical number of specimens evaluated for prostate biopsies is between 10 and 12. Hence, this policy inadvertently establishes a practice guideline, while capping reimbursement regardless of the number of specimens evaluated. Of note, though G0416 is set to be revalued, its current value is equivalent to reimbursement for the evaluation of about nine specimens billed with CPT 88305 (Level IV–Surgical pathology, gross and microscopic examination). Moreover, because the
government-established billing code is to be used regardless of the number of specimens, CPT 88305 will no longer be allowed for use for the examination of up to nine specimens when performing a prostate biopsy.

The concern with this policy is that it builds on the flawed logic underlying CMS’s CY 2014 decision to modify the prostate biopsy G-code descriptors so that they no longer distinguish prostate saturation biopsies from routine biopsy services. Prostate saturation biopsies have a much lower per unit cost and are typically performed on a larger volume of specimens for which efficiencies may be obtained when bundled. Moreover, they account for only one percent of prostate biopsy services but are now responsible for the valuation of 100 percent of prostate biopsies. Accordingly, CMS is multiplying its false efficiency assumptions regarding the bundling of routine prostate biopsies with its decision to further consolidate the already under-valued payment bundles.

Packaging of Ancillary Services into Payment for a Primary Service in Outpatient Hospitals and ASCs

CMS similarly sought to leverage efficiencies via standardized payment bundle schemes in the CY 2015 OPPS Final Rule. This year, the Agency finalized its plan to bundle the technical component of select ancillary services into the payment for the associated primary service when delivered in the hospital outpatient or ambulatory surgical center (ASC) setting. CMS defines “ancillary services” as “integral, supportive, dependent, or adjunctive to a primary service.” Beginning in January 2015, the Agency will conditionally package all ancillary services assigned to Ambulatory Payment Classifications (APCs) with a geometric mean cost of $100 or less. However, when ancillary services are furnished by themselves, they will continue to be reimbursed separately.
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**Clinical Support**
- Evidence-based Guidelines
- Computerized Provider Order Entry (CPOE)
- Test Formularies
- Order Set Review:
  - New Tests
  - Standing Orders
  - Bundled Tests
  - Exoteric Tests
  - Obsoleted Tests

**HIT Functions**
- HIT Functions
- HIT Tools
- Quality Control

**HIT Tools**
- HIT Tools
- Quality Control

**Quality Control**
- Quality Control
- Order entry data trend monitoring

**Test Ordering Continuum**
- Pre-Analytic
- Order
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**Pre-Analytic**
- Pre-Analytic
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- Collect
- Analytic
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- Post-Analytic
- Report
- Interpret

**Analytic**
- Analytic
- Process/Analysis
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- Post-Analytic
- Report
- Interpret

**Post-Analytic**
- Post-Analytic
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**Report**
- Report
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**Interpret**
- Interpret
- Automated Interpretation

**Evidence-based Guidelines**
- Evidence-based Guidelines

**Unsupervised Machine Learning**
- Unsupervised Machine Learning

**Proficiency Testing**
- Proficiency Testing

**Treatment Algorithms**
- Treatment Algorithms

**Include in Lab Report**
- Include in Lab Report

**Evidence-based Guidelines**
- Evidence-based Guidelines

**Unsupervised Machine Learning**
- Unsupervised Machine Learning

**Proficiency Testing**
- Proficiency Testing

**Treatment Algorithms**
- Treatment Algorithms

**Include in Lab Report**
- Include in Lab Report

**Laboratory Information System (LIS)**
- Automated Reflex Testing
- Reflex Testing Algorithms
- Automated Provider Feedback Loop:
  - Effectiveness in Guiding Treatment
  - Treatment Outcome

**Discrepant Results**
- Discrepancy Policy, Procedure, & Forms
- Discrepancy Patient/ Clinician Follow-Up Reminders

**Highlighted Actionable Results**
- Highlighted Actionable Results

**LIS-EHR Interoperability**
- LIS-EHR Interoperability

**Standardized List of Actionable Test Results**
- Standardized List of Actionable Test Results

**Patient Portal**
- Patient Portal

**Performance Dashboards**
- Performance Dashboards
Within the two pathology-specific APCs and blood transfusion APC impacted by this policy, there are more than 30 pathology services that qualify for bundling, including the following key services: Surgical Pathology (CPT 88304/88305/88307); Cytopathology (88173); Special Stains (88312/88313); FISH (88365/88120/88121); IHC (88342/88360/88361); Flow Cytometry (88184); and Frozen Section 1st Block (88331).

Nonetheless, it will be challenging to predict the exact impact until we know whether or not CMS is able to adequately estimate the typical volume of each ancillary service provided in conjunction with the designated primary service. Accordingly, absent the Agency’s ability to do so, inadequate valuation of the subsequent payment bundles may threaten reimbursement and patient access. Moreover, though this policy is an expansion of last year’s policy, in which CMS bundled more than 1,000 physician and laboratory services, CMS has yet to even analyze the impact of its CY 2014 OPPS bundle policy.

New and Revised CPT Codes for IHC Staining and FISH

Despite the concerns addressed above, the good news is that CMS has partially reversed course on another policy finalized last year that, while not exactly a bundled payment policy, strongly resembles one. In the CY 2014 PFS Final Rule, CMS replaced the existing CPT codes used to bill for immunohistochemistry (IHC) services with G-codes, thereby shifting the billing unit from the more granular slide-/antibody-level to the less granular specimen-level. In effect, CMS inadvertently bundled the reimbursement for IHC staining performed on each additional antibody per slide and each additional slide per specimen. Accordingly, multiple IHC stains performed as multiplex cocktails (multiple stains on multiple slides) are now reimbursed as a single stain. All the while, CMS overly exaggerated efficiencies gained and did not adjust reimbursement rates at the specimen-level to reflect the performance of IHC on multiple stains and/or slides.

Similar to IHC staining services, fluorescent in situ hybridization (FISH) services had recently been flagged as misvalued and cited for overutilization for financial gain. In order to prevent the creation of G-codes and the uncompensated shifting of the billing unit from the more granular probe-level to the less granular specimen-level, the pathology community united in the submission of cost data to the AMA RUC in support of the RUC’s development of CPT codes that more accurately reflect FISH services reimbursed at the specimen-level, including add-on codes and multiplex codes. In the Final Rule, CMS adopted all nine of the RUC-recommended CPT codes.

Transparency Initiative

While CMS’s strategy for reducing overutilization this year has largely been focused on bundled payment schemes, in the past the Agency has opted for across-the-board cuts to reimbursement—often with little to no warning. Accordingly, though CMS’s bundled payment policies are cause for concern, the Agency has finalized a policy aimed to provide more advanced notice of changes to physician reimbursement as well as enhanced provider involvement in the rate-setting process. In the CY 2015 PFS Final Rule, CMS finalized its “Transparency Initiative,” which restricts the use of interim final G-codes and ensures most new, revised and potentially misvalued codes are first introduced in the proposed rule, rather than the final rule without opportunity for comment. Accordingly, the drastic code changes that we have seen for CPT 88305 and IHC in past Final Rules, which gave providers limited to no warning and only two months to adjust, will hopefully be a thing of the past.

Modification of the Local Coverage Determination Process

Finally, CMS further upheld its commitment to transparency with its decision to abandon its CY 2015 proposal to expedite the Local Coverage Determination (LCD) process, which would have eliminated public meetings and opportunity for public comment. While this was of great relief to the pathology and laboratory community, concerns lingered regarding the administration of the LCD process. In fact, in this year’s final rule, CMS acknowledged that many of the comments received expanded beyond the scope of CY 2015 proposals to address concerns regarding policy changes finalized in the April 2014 passage of the Protecting Access to Medicare Act (PAMA). Accordingly, commenters voiced concerns with the Medicare Administrative Contractor (MAC)’s expanding scope of authority. Beyond reimbursement changes, commenters expressed concern that reimbursement decisions authorized by the MACs now provided CMS with a second mechanism by which to double reinforce “appropriate use” determinations. Citing Palmetto’s MolDX program, many commenters further argued that it is an over-exaggeration of a MAC’s authority to determine coverage based on determinations of superior test performance and that the Clinical Laboratory Improvement Amendment (CLIA) provides the best and most appropriate processes for assessing test-specific performance characteristics.

For more information on relevant policies in this year’s Final Rules, please reference the November ePolicy article at http://www.ascp.org/Advocacy/ePolicy-News-November-2014.html.

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