September 2, 2014

Marilyn B. Tavenner
Administrator Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
CMS-1613-P
P.O. Box 8013
Baltimore, MD 21244–1850

Subject: Medicare Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Systems; Proposed Rule for CY 2015. 79 FR 40,915 (July 14, 2014); CMS-1613-P; RIN 0938-AS15

Dear Administrator Tavenner:

On behalf of the American Society for Clinical Pathology (ASCP), I am writing to comment on the Medicare Hospital Outpatient Prospective Payment System (OPPS) Proposed Rule for CY 2015. The ASCP is a 501(c)(3) nonprofit medical specialty society representing more than 100,000 members. We are one of the nation’s largest medical specialty societies and the world’s largest organization representing the field of laboratory medicine and pathology. ASCP membership is uniquely diverse, consisting broadly of board certified pathologists, other physicians, clinical scientists, certified medical technologists and technicians, and educators. Together, our mission is to provide excellence in education, certification, and advocacy on behalf of patients, pathologists, and laboratory professionals to advance medicine and improve patient care.

In keeping with our CY 2014 comments, ASCP remains strongly opposed to CMS’s proposal to further expand the packaging of pathology and clinical laboratory services into the OPPS payment rates. In response to the Agency’s CY 2015 OPPS Proposed Rule, our comments are limited to the following proposals: (1) the conditional packaging of ancillary services assigned to Ambulatory Payment Classifications (APCs) with a geometric mean cost of up to $100; (2) the packaging of add-on services; and (3) the packaging of pathology professional services.

I. The Conditional Packaging of Ancillary Services Assigned to APCs with a Geometric Mean Cost of up to $100

Last year, as part of CMS’s CY 2014 Notice of Proposed Rulemaking (NPRM), the Agency extended its use of bundling within the OPPS by “packaging” more than 1,000 ancillary tests and services previously paid separately on the Physician Fee Schedule (PFS) and Clinical Laboratory Fee Schedule (CLFS). As a rationale for this policy, the Agency contended that packaging these services would reduce the incentive to provide unnecessary services in the outpatient setting.
In this year’s proposed rule, CMS is proposing to conditionally package additional ancillary services for CY 2015. Specifically, the Agency is proposing “to limit the initial set of APCs that contain conditionally packaged services to those ancillary service APCs with a proposed geometric mean cost of less than or equal to $100…” (prior to application of conditional packaging status indicator Q1). This conditional packaging proposal would be limited to certain ancillary services that are “integral, ancillary, supportive, dependent, or adjunctive” to a primary service, when provided on the same date and ordered by the same provider as the primary service. With this policy expansion, the Agency would conditionally package the technical component (TC) of more than 200 physician services and more than 30 pathology services (levels 1 and 2).

In response to last year’s proposal, ASCP raised concern (see attachment) about the implementation of an untested bundling scheme. Accordingly, we are once again concerned that this year’s proposed packaging expansion has not been subject to any testing in advance. Moreover, we are especially concerned that the Agency has not evaluated the impact of last year’s finalized packaging policies prior to proposing to expand upon them. We remain troubled that CMS has once again provided scant information to enable stakeholders to assess whether these services will be adequately reimbursed. We therefore assert that this undermines our ability to fully assess the proposal and to offer meaningful comments.

A large part of our concern is rooted in the fear that CMS may not be able to develop appropriate packaged reimbursement rates that accurately take into account the complex utilization patterns involved in providing pathology and laboratory services. ASCP asserts that many of the services impacted by this proposal may be medically necessary multiple times per day, depending on the primary service, the patient’s specific condition, and the severity of that condition. Failure to precisely craft packaged payment rates could lead to inaccurate, and likely insufficient, payment for services rendered. ASCP is concerned that if CMS is unable to properly value and estimate the typical number of ancillary services accompanying each primary service, that this could result in the undervaluation of critical pathology and clinical laboratory services and eventually their underutilization in the hospital setting. This could adversely affect patient care—and not just affecting patient diagnoses but the identification of the most appropriate and cost-effective therapeutic course of action as well. This could also lead to cost shifting outside of the hospital setting.

We believe that the conditional packaging proposal could adversely impact hospital laboratories’ financial outlook, which could, in turn, affect the service menu offerings of hospital laboratories. The reduced reimbursement may force hospital laboratories to further outsource some of the pathology services they now provide in-house. Such a development could be problematic for patient care, as it could negatively affect turn-around times on critical pathology and clinical laboratory services. This could have negative downstream implications for patient outcomes, should delayed turn-around times interfere with the most appropriate therapeutic treatments recommended. This could also result in financial implications for the Medicare program, as delayed lengths of stay not only threaten the long-term financial sustainability of the Medicare program but may also result in increased Medicare beneficiary cost-sharing obligations.

ASCP is also concerned that the expanded use of packaging for pathology and laboratory services will significantly increase administrative and billing burdens. We should note that pathology practices receive patient specimen referrals from multiple sources, not just hospitals but physician practices as well.
Accordingly, this initiative will require affected pathology practices and independent laboratories to purchase new or reconfigure existing billing/tracking systems to identify which tests and procedures are paid separately and which would be rolled into an outpatient package service. If finalized, this proposal would also require the retraining of pathologists and laboratory professionals, such as medical laboratory scientists, to ensure that appropriate billing practices are followed.

As a result of these concerns, ASCP urges CMS to withdraw this year’s conditional packaging proposal. Furthermore, we urge the agency to do a thorough and public review of the effects of last year’s packing of clinical laboratory and pathology services before considering any further expansion of its packaging policies to pathology and laboratory services.

II. The Packaging of Add-on Services

In this year’s CY 2015 OPPS Proposed Rule, CMS is also proposing to package “add-on” codes into a primary procedure bundle. As such, the Agency asserts that the add-on code is intended to serve as an extension of the primary procedure, meaning it is considered secondary or ancillary to the primary procedure. We are concerned that this classification is inappropriate for diagnostic pathology and many laboratory services, as it oversimplifies and fails to comprehend the importance of the service being performed. Packaging these add-on services is out-of-step with the historical paradigm that has recognized these unique services as distinct contributors to the physician work, clinical labor, medical supplies and equipment underlying the provision of a primary procedure. As such, in many cases, diagnostic pathology and laboratory services are as medically necessary as the primary service in question.

ASCP is very concerned that CMS has not valued the primary service to include the specific add-on services involved. We believe that it is fundamentally inappropriate to package medically necessary services in a primary procedure “bundle” that does not sufficiently compensate for the distinct resource costs involved in providing the overall service. ASCP is further concerned that CMS has provided insufficient information for stakeholders to adequately assess the impact of the proposal. Consequently, ASCP urges CMS to withdraw the proposed packaging of add-on codes outlined in the NPRM.

III. The Packaging of Pathology Professional Services

ASCP wishes to address four physician professional services that we hope CMS has proposed to package in error. In the NPRM, CMS proposed to unconditionally package CPT codes 88380 (Microdissection laser), 88381 (Microdissection manual), 88387 (Tissue exam molecular study) and 88388 (Tissue exam molecular study, add-on). In its proposal, the Agency outlines the packaging of a variety of CPT codes that can be found on the CLFS, excluding molecular services. Given that these four CPT codes, which may be used for molecular services, are reimbursed under the PFS, we seek clarification regarding whether or not they were included in this proposal in error.

Nonetheless, ASCP maintains that it is inappropriate to package any of these or any other professional pathology service into OPPS payment rates. Since CMS has not stated any plans to integrate physician
professional services into the OPPS for CY 2015, ASCP believes it would be inappropriate to incorporate any professional services into the OPPS packaging policies without clearly stating in the NPRM the Agency’s plans and rationale. Accordingly, **ASCP urges CMS to remove these codes from its packaging proposal.**

ASCP appreciate the opportunity to present these comments. If we can be of further assistance, please do not hesitate to contact me or Kaitlin Cooke, Senior Manager for Advocacy and Public Policy, at (202) 347-4450.

Sincerely,

Matthew Schulze
Director of Government Relations
ASCP