



November 20, 2017

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Submitted electronically via CMMI_NewDirection@cms.hhs.gov

RE: Innovation Center New Direction – Request for Information

Dear Ms. Verma,

The College of American Pathologists (CAP) appreciates the opportunity to respond to the agency's request for information on the Center for Medicare and Medicaid Innovation (CMMI) planned new direction for the Innovation Center. As the world's largest organization of board-certified pathologists and leader provider of laboratory accreditation and proficiency testing programs, the CAP services patients, pathologists and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine.

Guiding Principles

The CAP is encouraged by the prospect of a new direction for the Innovation Center, particularly given challenges pathologists have faced with engagement in alternative payment and delivery models. CMS notes that existing partnerships with healthcare providers, clinicians, states, payers, and stakeholders have generated important value and knowledge, yet pathologists have not enjoyed the same level of collaboration in fostering models appropriate for our specialty or that adequately account for the value of pathology services. Without alternative payment models (APMs) – especially Advanced Alternative Payment Models (A-APMs) – pathologists are limited to participation in CMS' Quality Payment Program (QPP) via the Merit-Based Incentive Payment System (MIPS) track.

In addition to its proposed guiding principles, we urge CMMI to include the following:

- **Engage stakeholders at all phases of model development.** CMMI must use transparent, subregulatory processes, such as requests for comment and information, to meaningfully engage stakeholders at all phases of model development. In recent years, CMMI established several models through rulemaking, leaving little opportunity for substantive modifications given the challenge of meeting the "logical outgrowth" test. While the models are now withdrawn, cancelled or significantly modified, problem areas could have been addressed at the outset with early stakeholder engagement and *in advance* of rulemaking.
- **Evaluate proposals for inclusion of relevant non-patient-facing specialists and services.** Non-patient-facing clinicians such as pathologists, including the services they provide, are pivotal to the diagnosis, treatment, and ongoing management of a broad array of acute and chronic diseases. Robust pathologist integration in alternative payment and delivery models would assist with appropriate utilization of laboratory testing (e.g., targeting unnecessary and costly test repetition and phlebotomy, and focusing on appropriateness of tests sent to reference laboratories), not to mention advancing medical science in the origins and treatment of disease through personalized medicine delivered through genetic testing innovations and targeted treatment adoptions. Based on the current inventory of APMs, the inclusion of non-patient-facing clinicians has been severely overlooked. To improve the value of Medicare's APM inventory and to increase the availability of APMs in which pathologists may participate, CMMI should evaluate whether proposed models have accounted for the role of pathologists and



pathology services. Where pathologists are omitted, developers should be encouraged to collaborate with the specialty to improve the model.

- **Emphasize the use of specialty-developed quality measures and specialty-developed clinical data registries.** Given the emphasis on development and prioritization of specialty-focused quality measures and use of specialty- or disease-developed qualified clinical data registries (QCDRs) as part of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), the CAP made tremendous investments in these activities. Similar to the above, we believe our measures and QCDR should be incorporated in new and existing APMs given their importance in understanding the quality and performance for relevant episodes of care that involve the use of pathology services. In addition, we encourage CMMI to emphasize the use of specialty-developed QCDRs in new and existing models, where relevant because specialty societies' registries have emerged as prime sources of representative clinical data, and the major aggregators of data. QCDRs that serve more limited purposes or are used for other business purposes often do not provide representative data on which to base new models.
- **Allow for voluntary – not mandatory – participation in APMs.** CMMI should not mandate participation in alternative models of payment and delivery. Rather, the agency should ensure models are available for a multitude of specialists, including pathologists, and incentivize participation.

Proposed Models

Expanded Opportunities for Participation in Advanced APMs

Pathologists are severely limited in their ability to engage with APMs, and particularly A-APMs. According to CMS, only 136 (0.1 percent) out of 13,947 pathologists in Medicare are expected to reach “qualifying participant” (QP) status in year one of the Quality Payment Program (QPP)¹. This must be addressed to ensure pathologists can participate in the QPP beyond MIPS, which some congressional advisory bodies seek to eliminate². Non-patient-facing clinicians need additional opportunities to participate and demonstrate value.

In 2014, we met with CMMI leadership to discuss the role of pathologists in care coordination, noting that daily medical decisions made by pathologists and the laboratories they direct produce critical diagnostic information. Specifically, pathologists and the data they provide serve as a key influence on healthcare, driving an estimated 70% of clinical decision making. They are central to coordinated care teams, helping to ensure appropriate test utilization/selection and optimal therapy options, which is important to improving quality and resource use. As laboratory directors, pathologists:

- **Interact with members of the medical staff regarding issues of quality, and test availability:** Pathologists serve on numerous quality councils including Infection Control, Transfusion Medicine, Surgical Quality Council, Internal Medicine Council, Diagnostic Service Line Council and work with various specialties to determine appropriate quality tests and test algorithms for the patients they serve.
- **Design protocols and establishing parameters for performance of clinical testing:** This includes all clinical testing except for FDA approved Laboratory Developed Tests which require additional protocol designs and validations at the individual laboratory.
- **Recommend appropriate follow-up diagnostic tests:** Pathologists review protein electrophoresis and recommend additional targeted protein evaluation such as immunofixation. Pathologists assist other physicians by recommending appropriate

¹ <https://www.federalregister.gov/d/2016-25240/page-77518>

² <http://medpac.gov/docs/default-source/default-document-library/mips-oct-2017-final.pdf?sfvrsn=0>



further coagulation work up in patients with unexplained abnormal Prothrombin time (PT) or Partial thromboplastin time (PTT) blood tests.

- **Evaluate clinical laboratory data:** Pathologists review abnormal hematology histograms and values and perform microscopic peripheral smear reviews and interpretations
- **Assure that tests, examinations, and procedures are properly performed, recorded and reported:** Pathologists perform chart or Electronic Medical Record (EMR) test validation reviews
- **Advise regarding aberrant results:** Pathologists directly contact ordering physician/care provider when unexpected results or diagnoses are rendered. Pathologists develop critical value lists for immediate communication with the physician.
- **Select, evaluate, and validate test methodologies:** Pathologists are involved in the selection of appropriate testing to be performed in local hospital or independent laboratories, and optimal resources for reference laboratory testing, through evaluation of the RFP vendor process. Pathologists evaluate all of the clinical statistical data generated during validation of new test methodologies and review confirmation data in their laboratory against manufacturer's claims before patient testing is approved.
- **Direct, perform, and evaluate quality assurance and control procedures:** Pathologists, as part of oversight of a required Quality Management (QM) program, review all Quality Control (QC) data and Quality Assurance (QA) monitors and recommend and implement necessary process changes as needed.
- **Evaluate clinical laboratory data:** Serving as integrators of laboratory data and information, pathologists can identify high-risk patients, employ pattern recognition, risk factor identification and other clinical judgments and utilization observations, including peer comparisons to assist with chronic disease management such as diabetes and detection of other diseases, including cancer.

Pathologists are committed to responsible stewardship of federal health programs; therefore, we urge CMMI to work with the CAP on ways to incorporate our ideas into new and existing models. Though the majority of pathologists are considered non-patient-facing, our value in innovating new payment and delivery models should be actively considered. We look forward to the opportunity to speak with you and the new CMMI leadership in the coming months on ways to engage pathologists in models.

Physician-Specialty Models

As noted above, pathologists are poised to address a great number of quality and cost challenges that persist in the Medicare program and beyond. While models focused exclusively on pathology services may take time to develop (based on our attempts at developing episode-based cost measures) our value in many other models, particularly those focused on specialty care, may be more evident.

While laboratory spending alone is unlikely to represent a large portion of a model or episode spend, the active engagement of pathologists can possibly lead to lower total spend. The extensive influence of laboratory testing on clinical decision making uniquely positions pathologists to assist clinicians in achieving their objectives, particularly in eliminating waste and inefficiencies in innovative evidence-based ways. These factors make pathologists integral to the team involved in managing an episode of care and achieving quality outcomes.

To a large extent, alternative payment and delivery models that have been forwarded previously have overlooked laboratory services as essential services to certain conditions and diseases and not afforded pathologists the opportunity to extend their contributions that are so important to aligned and coordinated team-based care, population health and health care systems. To that end, we urge CMMI to evaluate whether proposed models – including



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those developed internally and externally to the agency – have accounted for the role of pathologists and pathology services. Where pathologists are omitted, model developers should be encouraged to collaborate with our specialty to improve the model.

We appreciate the opportunity to provide comments on the aforementioned issues of importance to the CAP. Should you have any questions, please contact Pam Johnson at 202-354-7132 or pajohns@cap.org.