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Education. Innovation & Improved Patient Care. Advocacy.
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The Association for Molecular Pathology's Comments on Section 1834A of the Protecting Access to Medicare Act of 2014

I. AMP introduction

The Association for Molecular Pathology (“AMP”) is an international medical and professional association representing over 2000 physicians, doctoral scientists, and medical laboratory scientists. Our members are dedicated to the development and implementation of molecular pathology procedures for the benefit of our patients in a manner consistent with the highest standards established by the Clinical Laboratory Improvement Amendments (CLIA), the College of American Pathologists (CAP), the American College of Medical Genetics (ACMG), and the Food & Drug Administration (FDA).

AMP members populate the majority of clinical molecular pathology laboratories in the United States, and our efforts are central to the generation of novel, high quality, molecular procedures that are applied daily in medical decision-making. We perform assays that we design, develop and validate within our laboratories to establish diagnoses, prognoses, and risk of future disease, to predict response to therapy, to monitor and otherwise assist in the management of our patients. Our work encompasses molecular oncology, inherited disease, and histocompatibility testing. In addition to developing and implementing such procedures, AMP members are experts in the interpretation of these assays.

The laboratories and settings in which AMP members work are varied in size, scope of testing, nature of services provided, and their respective missions. Many AMP members are faculty at nonprofit academic medical centers, where their testing services are integrated with combined institutional missions of teaching, patient care, and research. These AMP members emphasize the comprehensiveness of their offerings, and the provision of important interpretative and consultative services. Other AMP professional members are employees of instrument and test kit manufacturers. Still others work for large volume, high throughput, commercial laboratories that are dedicated to providing accurate technical results at low cost. AMP believes that all of our members have important roles to play in the provision of molecular services, and that each makes vital contributions in her or his own way to patient care, innovation, and the richness and vibrancy of the field of molecular pathology.

Thank you very much for the opportunity to provide comments to the Centers for Medicare & Medicaid Services on the implementation of regulations for Section 1834A of the Protecting Access to Medicare Act of 2014 (PAMA), entitled “Improving Medicare Policies for Clinical Diagnostic Laboratory Tests.”

II. AMP requests that CMS interpret PAMA's requirements in a manner that will minimize the reporting burdens on clinical laboratories.

PAMA requires reporting of highly granular payment data that will be difficult or impossible for hospital and other small and physician owned laboratories to provide using their current software

systems. Because molecular pathology testing is often performed on outpatients, and is not included in the Hospital Outpatient Prospective Payment System (OPPS), PAMA's reporting burdens could prove devastating to hospital molecular pathology laboratories. The potential penalties for reporting errors are extraordinarily severe (\$10,000 per day for each) and disproportionate to nature and the significance of such mistakes. The combination of onerous reporting requirements, enormous potential penalties from errors, and limited reimbursement risks discouraging hospitals and smaller laboratories from engaging in reportable testing, including molecular pathology testing. This would harm Medicare beneficiaries by reducing patient access and choices in testing, decreasing innovation, inhibiting research, as well as eliminating the comprehensive, consultative services often provided by hospital and other local molecular pathology and general clinical laboratories. Finally, payers such as insurance companies are best able to provide pricing data, and CMS should attempt to find a regulatory solution that obtains significant components of these data from payers.

III. CMS should define “applicable laboratories” so as to exempt hospitals and other small laboratories, academic medical centers, health systems, and these entities’ outreach testing performed on non-patients, from PAMA’s reporting requirements.

PAMA defines an “applicable laboratory” as a laboratory that derives a majority of its Medicare revenue from the Clinical Laboratory Fee Schedule or the Physician Fee Schedule, but does not define the term “laboratory.” Clinical laboratories may be defined by the Taxpayer Identification Numbers of the institutions in which they reside, which would exempt most hospitals from reporting. However, we ask that in drafting regulations CMS go beyond Taxpayer ID to consider institutional ownership structure in a manner that will further reduce the applicability of PAMA's reporting burdens for hospital testing performed for non-patients who utilize hospital outreach services.

IV. CMS should establish regulations that require deliberate or willful misrepresentation for the imposition of civil monetary penalties, and which clearly state that unintentional reporting omissions will not be penalized.

PAMA's statutorily allowed penalties apply to mere “omissions,” and are grossly disproportionate to the nature and significance of covered mistakes or infractions. The prospect of such enormous fines will create a chilling effect on the willingness of many institutions to perform reportable testing. Therefore, we respectfully ask CMS to implement regulations that remove the threat of penalties on laboratories that make good faith efforts to comply with reporting requirements using preexisting informatics systems, and clarify that laboratories are not required to purchase new software or systems to comply with these regulations.

V. CMS should attempt to use existing regulatory authority to obtain payment data from insurers and other payers.

Payers such as insurance companies are best able to provide accurate pricing and volume data. The most efficient and effective way for CMS to obtain this information is to obtain it from such entities. Can CMS utilize other vehicles, e.g. the quality reporting provisions of Section 2717 (a) of the Affordable Care Act, to obtain laboratory test payment and volume data about hospitals, academic medical centers, and health systems? Although the statute only sets forth reporting requirements for clinical laboratories, we ask that CMS attempt to find a way to use a combination of exemptions of certain laboratories and pre-existing regulatory authority to obtain payment and volume data from payers of those services.

VI. CMS should establish low volume, low expenditure thresholds that minimize the reporting burdens on hospital and other small molecular pathology laboratories, should these laboratories be required to report test payment and volume data.

PAMA gives the HHS Secretary the authority to establish low volume or low expenditure thresholds that exclude laboratories from the definition of applicable laboratory. Therefore, we ask that CMS implement volume and threshold levels that exempt hospital and other limited size molecular pathology laboratories from reporting burdens, should the term laboratory be defined in a manner that would require that such laboratories to report test payment and volume data.

VII. CMS should limit data collection periods to minimize changes or fluctuations in payment rates, and to lessen the reporting burden on laboratories.

The Secretary has discretion to specify data collection periods. We ask that CMS limit the length of these data collection periods so as to minimize the number of data points and therefore the reporting burden placed on laboratories.

VIII. CMS should only require reporting of discounts if such discounts are directly attributable and readily linked to a specific test, or can be apportioned using a simple formula.

The “applicable information” specified in the Statute includes “discounts, rebates, coupons, and other price concessions.” However, discounts could in some circumstances prove difficult to calculate or properly allocate to individual tests. Therefore, we ask that CMS design reporting requirements in such a manner so as to only require reporting of price reductions that can be readily established and allocated to specific tests directly, or by using simple, straightforward calculations. Moreover, CMS should clarify that payment denials (i.e., a price of “0”) will not be included in the price and volume data used to calculate the weighted median for a given test.

IX. CMS should only require reporting for tests for which individual CPT test codes can be directly submitted to the payer, and for which payment is reported back to the laboratory in itemized fashion on a code-by-code basis.

The Statute excludes from reporting payment information about tests that are paid on a capitated or similar payment basis. Because of the difficulty in establishing individual pricing in some payment arrangements, we ask that CPT codes form the basis of reporting, and that CMS only require reporting for tests for which individual CPT test codes can be directly submitted to the payer and reported back to the laboratory in itemized fashion on a code-by-code basis.

X. CMS should as much as possible utilize Category I and Category III CPT codes, including MAAA Appendix 0 and MAAA category I CPT codes, to satisfy statutory instructions for issuance of HCPCS codes.

Because of their broad applicability, simplicity, clarity, and widespread use, we ask that CMS continue to utilize CPT codes whenever possible for the issuance of all statutorily required HCPCS codes, including any unique identifiers used for test tracking. Further, consistent with Section 1833(h) of the Social Security Act and Code of Federal Regulations Section 42 C.F.R. 414.508, we ask that the regulations affirm that only specifically assigned HCPCS codes for individual tests, when available, are lawfully permitted to be used for Medicare billing.

XI. In order to encourage the most appropriate use of Medicare funds, we ask that CMS narrowly define the category of Advanced Diagnostic Laboratory Tests.

Section 1834A(d)(5) of the Statute defines Advanced Diagnostic Laboratory Tests as laboratory tests that are offered and furnished by single laboratories and either utilize an algorithm to combine multiple biomarkers to yield a single patient-specific result or are cleared or approved by the Food and Drug Administration. In addition, section 1834A(d)(5)(C) vests some discretion with the Secretary to define Advanced Diagnostic Laboratory Tests based on “other similar criteria established by the Secretary.” In order to ensure that patients receive clinically meaningful tests, we ask that CMS decline to include additional tests as Advanced Diagnostic Laboratory Tests, and narrowly define this category.

XII. CMS should recognize the contribution to patient care made by a test in order to ensure its appropriate valuation.

When establishing payment rates during the gapfilling process, Section 1834A(c)(2)(E) of the Statute empowers the Secretary to consider other “criteria the Secretary determines appropriate” in addition to resources required to perform a test, payment amounts of other payers, and “charges, payment amounts, and resources required” for other comparable and relevant tests. These factors could include direct cost savings from test use, improvements in patient outcomes, and a test’s overall contribution to patient management. For example, *KRAS* mutation testing in colon cancer patients decreases costs and eliminates potential morbidity by restricting the use of anti-*EGFR* therapy to patients in whom it is most likely to work. We therefore ask CMS to incorporate such factors in establishing payment rates for gapfilled tests. This approach will recognize the importance and value of diagnostics in patient care, and will stimulate innovation that will improve the health of Medicare beneficiaries.

XIII. We strongly urge CMS to include molecular pathologists and molecular laboratorians, as well as other pathologists and pathologist experts in laboratory accreditation, on the mandated Expert Advisory Panel.

Many of our most important new tests lie in the subspecialty of molecular pathology. Subspecialists in molecular pathology have extensive experience developing, validating, performing, and applying molecular and other laboratory tests. Moreover, molecular pathologists have primary specialty training and experience in laboratory medicine (clinical pathology) and/or anatomic pathology and are general experts in laboratory science.

Therefore, molecular pathologists are ideally suited to serve as members of the Expert Advisory Panel in order to provide input on the establishment of payment rates and the factors used in determining coverage for new clinical diagnostic laboratory tests, as well as to provide recommendations to the Secretary of HHS regarding payment for new laboratory tests.

XIV. CMS should maintain the current system of utilizing multiple contractors to process test claims and establish test coverage policies.

In section 1834(g)(2), the Statute gives CMS the authority to designate between one and four Medicare Administrative Contractors (MACs) to either establish coverage policies, or to establish coverage policies and process claims for diagnostic tests. We believe the current system of utilizing multiple contractors to establish coverage policies and process claims is desirable, as the combined, independent assessments of multiple contractors are likely to yield the most accurate pricing. Further, the use of multiple contractors optimizes knowledge about tests and enhances perspective regarding

coverage decisions. Therefore, we ask that CMS preserve the current system that utilizes multiple contractors to determine coverage policies and process claims for diagnostic laboratory tests. However, if CMS chooses to limit the number of contractors to which it assigns responsibility for coverage decisions and payment processing, we ask that CMS utilize the maximum allowed number of 4 contractors for the reasons described in the preceding paragraph. A single contractor's coverage decision would become a de facto national coverage decision, without the thoroughness of review and safeguards the existing National Coverage Determination process brings. Because of the weakened review process and the absence of such safeguards, CMS would thereby delegate excessive authority to one or a small number Medicare contractors.

XVI. Conclusion

Thank you again for the opportunity to provide comments on the implementation of regulations for the clinical laboratory provisions of the Protecting Access to Medicare Act of 2014. AMP asks that these regulations be implemented in a manner that will minimize the reporting burden for hospitals, academic medical centers, small laboratories, and health systems, in order to preserve the richness, vibrancy, and innovation that have allowed the field of molecular pathology to make enormous contributions to the health and well-being of Medicare beneficiaries and the population at large.