March 29, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Room 314G
Washington, DC 20201

Re: Ratesetting for New Diagnostic Tests Under PAMA §216

Dear Administrator Verma:

On behalf of AdvaMedDx, we are writing to the Centers for Medicare & Medicaid Services (CMS) about an issue of concern relating to rate-setting for new tests paid on the Clinical Laboratory Fee Schedule (CLFS).

AdvaMedDx represents the world’s leading diagnostics manufacturers by advocating for the value and power of medical diagnostic tests to promote wellness, improve patient outcomes, and advance public health in the United States and abroad. AdvaMedDx member companies produce innovative, safe and effective diagnostic tests that facilitate evidence-based medicine, improve quality of care, promote wellness, enable early detection of disease and often reduce health care costs.

Since the implementation of §216 of the Protecting Access to Medicare Act (PAMA), and particularly since January 1, 2019, AdvaMedDx members have identified a concern about payment amounts for new tests that are established by CMS using a crosswalking methodology. The concern is that a code for a new test, when crosswalked to an existing test code that is slated to receive payment reductions under PAMA, will automatically also receive those payment reductions, even though no private payer data collection and reporting has occurred for the new test code. We provide more detail about this issue below.

Background

On January 1, 2018, when CMS implemented new Medicare payment amounts for tests paid on the CLFS based on the weighted median of the private payer rates reported by laboratories, payment amounts for the majority of the existing tests codes on the CLFS were reduced. Many of these test codes will receive payment reductions of 30-40 percent or more over several years,
although the statute limits reductions for any individual test to 10 percent per year for the years 2018 through 2020 (and 15 percent per year for 2021 through 2023).

Because the law requires CMS to collect private payer rates every three years, CMS will not have any private payer data for new tests until the next data collection and reporting periods. Therefore, the statute requires CMS to establish the CLFS rate for a new test by either crosswalking to an existing, similar test, or by using gapfilling (contractor pricing with specific rules and guidance), when no similar test exists.

**Issue**

When a new test is crosswalked to an existing test that is subject to a payment reduction in future years, payment for the new test will be reduced as well, even though no private payer pricing data has been reported to CMS for the new test.

Furthermore, depending upon where in the private payer data collection cycle the new service is priced and the magnitude of the reduction for the test being used as the source of the crosswalk, payment may be reduced by as much as 10 or 15 percent per year for as much as three consecutive years.

It is inequitable to subject a new test, for which private payer data are unknown, to a payment reduction of as much as 10 percent within one year of the test coming onto the market based on the way payments may be changing for another test code that is similar to the new test code.

New tests on the fee schedule should be accorded a level of price stability for some time period, allowing time to establish a customer base to recognize economies of scale and other efficiencies. Absent this time period before price reductions occur, the viability of new tests for the Medicare population will be threatened.

**Proposed Solution**

AdvaMedDx asks CMS to undertake rulemaking to protect payments for new tests from immediate payment reductions for a period of time (for example, in the period of time prior to the next data collection period) when that new test is crosswalked to a code that is scheduled for a reduction based on private payer data reporting. The PAMA statute provides that CMS determine payment amounts for new tests (that are not advanced diagnostic laboratory tests, or ADLTs) “…using cross-walking (as described in section 414.508(a) of title 42, Code of Federal Regulations [CFR], or any successor regulation).”

Under §1871 of the Act, the Secretary has broad rulemaking authority to implement the Medicare program including updating existing regulations (and methodologies adopted pursuant to those regulations) except when specifically precluded by the statute. For instance, §1833(t)(21)(B)(i) of the Act, explicitly requires the Secretary to use the regulatory definition of

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1 1834A(c)(1)(A) of the Social Security Act (the Act).
“‘off-campus outpatient department of a hospital’…in effect as of the date of enactment of this paragraph…” The PAMA provision did not similarly limit the Secretary’s authority to carry out rulemaking with respect to crosswalking, which allows CMS to undertake the rulemaking we are requesting.

Using its rulemaking authority to determine how it will apply crosswalking, we urge CMS to include a proposal in the upcoming Physician Fee Schedule proposed rule that revises 42 CFR §414.508(b) such that payment reductions may not apply to new tests priced using crosswalking for 2020 and subsequent years. We further request that the rule remove reductions applied to new tests for 2018 and 2019 when determining 2020 CLFS payment rates.

AdvaMedDx greatly appreciates the opportunity to provide these comments. Please contact me or Chandra Branham, JD, at cbranham@advamed.org if you have additional questions or need additional information.

Sincerely,

Susan Van Meter
Executive Director
AdvaMedDx