effective January 1, 2017, to state that services and supplies furnished incident to CCM and TCM services can be furnished under general supervision of an RHC or FQHC practitioner, consistent with § 410.26(b)(5), which allows CCM and TCM services and supplies to be furnished by clinical staff under general supervision when billed under the PFS. We propose to further revise § 405.2413(a)(5) and § 405.2415(a)(5) to state that services and supplies incident to the services of a physician, NP, PA, or CNM are furnished under the direct supervision of a physician, NP, PA, or CNM, except for TCM, General Care Management, and Psychiatric CoCM services, which can be furnished under general supervision of a physician, NP, PA, or CNM when these services or supplies are furnished by auxiliary personnel, as defined in § 410.26(a)(1).

B. Part B Drug Payment: Infusion Drugs Furnished Through an Item of Durable Medical Equipment (DME)

Section 303(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003) revised the payment methodology for most Medicare-covered Part B drugs and biologicals by adding section 1847A to the Act, which established a new average sales price (ASP) drug payment methodology beginning January 1, 2005. However, section 303(b) of the MMA specified payments for certain drugs using methodologies other than the ASP pricing methodology. Specifically, section 303(b) of the MMA added section 1842(o)(1)(D)(i) of the Act that required that an infusion drug furnished through an item of DME covered under section 1861(n) of the Act be paid 95 percent of the average wholesale price (AWP) for that drug in effect on October 1, 2003.

Section 5004(a) of the 21st Century Cures Act (Cures Act) (Pub. L. 114–255, enacted on December 13, 2016) revised sections 1842(o)(1)(C) and (D) of the Act, changing the payment methodology for DME infusion drugs from being based on AWP to the methodologies in sections 1847, 1847A, 1847B, or 1881(b)(13) of the Act, as the case may be for the drug or biological. To implement the pricing changes required by section 5004(a) of Cures Act, which modifies the payment for DME infusion drugs to the amount under section 1847A of the Act (ASP payment methodology), by the statutorily mandated effective date of January 1, 2017, we incorporated the ASP-based infusion drug payment amounts into the January 2017 quarterly ASP drug pricing files and instructed claims processing contractors to use the updated payment limits for DME infusion drugs.

To conform regulations with the new payment requirements in section 5004(a) of the Cures Act as they pertain to section 1847A of the Act, we propose revising § 414.904(e)(2). Currently, this describes an exception to ASP-based payments and requires pricing DME infusion drugs at 95 percent of the 2003 AWP. Consistent with section 5004(a) of the Cures Act, the proposed revision limits the exception to infusion drugs furnished before January 1, 2017. In addition, we propose at § 414.904(e)(2) to delete the phrase ''and is not updated in 2006.'' We believe this language is not relevant since there was no update for pricing DME infusion drugs in 2006, and the proposed revision will serve to simplify the language. Effective January 1, 2017, payment limits for these drugs are determined under section 1847A of the Act.

C. Solicitation of Public Comments on Initial Data Collection and Reporting Periods for Clinical Laboratory Fee Schedule

1. Background on Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule

In the final rule published in the June 23, 2016 **Federal Register** (81 FR 41036) entitled, ''Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System,'' we implemented the requirements of section 1834A of the Act, which requires extensive revisions to the Medicare payment, coding, and coverage for clinical diagnostic laboratory tests (CDLTs) paid under the Clinical Laboratory Fee Schedule (CLFS).

Under the CLFS final rule, reporting entities are required to report to CMS certain applicable information for their component applicable laboratories. The applicable information includes, for each CDLT furnished during a data collection period, the specific HCPCS code associated with the test, each private payor rate for which final payment has been made, and the associated volume of tests performed corresponding to each private payor rate. In general, the payment amount for a test on the CLFS furnished on or after January 1, 2018, will be equal to the weighted median of private payor rates determined for the test, based on the applicable information that is collected during a data collection period and reported to us during a data reporting period.

In the CLFS final rule, we established a data collection period that is the 6 months from January 1 through June 30 during which applicable information is collected and that precedes the data collection period. We established a data reporting period that is the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period. The first data collection period was January 1, 2016 through June 30, 2016. The first data reporting period was January 1, 2017 through March 31, 2017. This 6-month data collection period and 3-month data reporting period schedule will be repeated every 3 years for CDLTs that are not advanced diagnostic laboratory tests (ADLTs), and every year for ADLTS that are not new ADLTs.

For the first data reporting period, industry feedback suggested that many reporting entities would not be able to submit a complete set of applicable information to us by the March 31, 2017 deadline, and that entities required additional time to review collected data, address any issues identified during such review, and compile the data into our required reporting format. As a result, on March 30, 2017, we announced that we would exercise enforcement discretion until May 30, 2017, with respect to the data reporting period for reporting applicable information under the Medicare CLFS and the application of the Secretary's potential assessment of civil monetary penalties for failure to report applicable information.[1] The enforcement discretion applied to entities that were subject to the data reporting requirements adopted in the CLFS final rule (81 FR 41036). We noted in the announcement that the 60-day enforcement discretion period was the maximum amount of time we could permit to still have sufficient time to calculate the CLFS payment rates scheduled to go into effect on January 1, 2018.

The announcement stated that the enforcement discretion period would not prevent reporting entities prepared to report applicable information from doing so before May 30, 2017. We explained in the announcement that we were committed to the successful implementation of the new private payor rate-based CLFS and looked forward to working with the laboratory industry to ensure accurate payment rates. Over the coming months, we will be analyzing the applicable information we received, holding our Annual

[1] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/2017-March-Announcement.pdf.*

Laboratory Public Meeting, meeting with the Advisory Panel for Clinical Diagnostic Laboratory tests, and posting preliminary payment rates.

2. Solicitation of Public Comments on Medicare Clinical Diagnostic Laboratory Tests Payment System Initial Data Collection and Reporting Periods

To better understand the applicable laboratories' experiences with the data reporting, data collection, and other compliance requirements for the first data collection and reporting periods, we are interested in public comments from applicable laboratories and reporting entities on the following questions:

- Was the CMS data reporting system easy to use? Please describe your overall experience with navigating the CMS data reporting system. For example, describe the aspects of the CMS data reporting system that worked well for your reporting entity and/or any problems the reporting entity experienced with submitting applicable information to us.
- Did the applicable laboratory (or its reporting entity) request and receive assistance from our Help Desk regarding the CMS data reporting system? Please describe your experience with receiving assistance.
- Did the applicable laboratory (or its reporting entity) request and receive assistance from the CMS CLFS Inquiries Mailbox regarding policy questions? Please describe your experience with receiving assistance.
- Did the applicable laboratory (or its reporting entity) use the subregulatory guidance on data reporting provided on the CMS CLFS Web site? [2] If so, was the information presented useful?
- Was the information that the applicable laboratory was required to report readily available in the applicable laboratory's record systems?
- Did the reporting entity have a manual, automated, or semi-automated remittance process for data reporting?
- If the reporting entity used a manual or semi-automated remittance process for data reporting, what percentage of the process was manual?
- How much time (hours) was required to assemble and report applicable information to CMS?
- Is there any other information that will inform us regarding the reporting, recordkeeping, and other compliance requirements from the first data collection and reporting periods?

We believe that industry feedback on these issues will help inform us regarding potential refinements to the private payor rate-based CLFS for future data collection and reporting periods. We welcome comments on these questions from the public.

D. Payment for Biosimilar Biological Products Under Section 1847A of the Act

In the CY 2016 Physician Fee Schedule (PFS) final rule with comment period, we finalized a proposal to amend the regulation text at § 414.904(j) to make clear that the payment amount for a biosimilar biological product is based on the ASP of all NDCs assigned to the biosimilar biological products included within the same billing and payment code (80 FR 71096 through 71101, November 16, 2015 **Federal Register**). In general, this means that products that rely on a common reference product's biologics license application are grouped into the same payment calculation for determining a single ASP payment limit and that a single HCPCS code is used for such biosimilar products. The regulation went into effect on January 1, 2016.

The comments received on the rule revealed that stakeholders had varying opinions about payment for biosimilar biological products under Part B. The commenters included individuals, pharmaceutical manufacturers, patient advocate groups, providers, insurers, and members of Congress. A number of commenters opposed a single payment amount for all biosimilars that rely on a common reference product. Most of these commenters believed that the proposed regulation would decrease incentives for biosimilar development and that grouping payment for biosimilar biological products is inconsistent with the statute. Some commenters also expressed concerns that prescribers' choices will be limited, that tracking or pharmacovigilance activities will be impaired, and that innovation and product development will be harmed, leading to market consolidation and increased costs for biosimilar biological products. Many commenters who opposed our proposal suggested that we determine a payment amount for each biosimilar biological product. These stakeholders have expressed concerns that the finalized policy restricts and threatens the viability of their business models and expressed support for a market-based solution. Some of these stakeholders believe that determining a payment for each biosimilar product by using individual HCPCS codes, would drive and reward innovators producing potential cost savings, of at least 10–15 percent compared to the reference biologic ASP, necessary for biosimilar products to compete with the reference biological.

However, some commenters supported our proposed regulation, stating that the potential marketplace for biosimilar biological products is large and it is less risky than the marketplace for reference biologicals. Commenters also expressed concern that separate payment for each biosimilar biological product would result in less competition among manufacturers, which in turn could lead to higher payment amounts for Medicare and beneficiaries. Some commenters stated that separate billing codes could be perceived as a type of price protection and could artificially increase prices for biosimilars. Commenters who supported the proposed regulation suggested that we remain mindful of our policy as the biosimilar biological product marketplace evolves. Several commenters requested that policy decisions be delayed while issues such as naming conventions and interchangeability standards are finalized by the FDA.

As CMS expected, since the regulation was finalized, the biosimilar product marketplace has continued to grow, and several biosimilar biological products that are paid under Part B have been licensed, including one product that we expect will share a HCPCS code with another biosimilar biological product. Over the next year or so, we anticipate that several more biosimilar biological products will be licensed for use in the United States and that during the following years, the marketplace will continue to grow steadily. We also anticipate that biological products will continue to be heavily utilized in Part B. At the same time, we are aware of concerns that current policy may discourage development of new biosimilars and other innovation in this area potentially resulting in higher costs over time due to a lack of competition in the market place.

In the 2016 PFS final rule, we stated that it is desirable to have fair reimbursement in a healthy marketplace that encourages product development (80 FR 71101). CMS seeks to promote innovation, to provide more options to patients and physicians, and competition to drive prices down, recognizing that even though these two goals may be difficult to achieve concurrently, to delink them would be counterproductive.

Although we believe that the United States biosimilar biological product marketplace is still in an early phase (because only a few products are on the market), we are interested in assessing

[2] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.*