CVSHealth

VIA Electronic Submission
http://www.regulations.gov

September 8, 2015

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1631–P
P.O. Box 8013
Baltimore, MD 21244–8013.

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016

CVS Health, on behalf of its subsidiaries and affiliated entities, appreciates the opportunity to comment on the proposed rule on Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 ("proposed rule").
CVS Health is a pharmacy innovation company helping people on their path to better health. Through our more than 7,800 retail pharmacies, more than 900 walk-in clinics, a leading pharmacy benefits management (PBM) business with more than 65 million members, and an expanding specialty pharmacy services business, we enable people, businesses and communities to manage health in more effective ways, by lowering the cost of and increasing the access to quality health care. The Pharmacy Services Segment provides a full range of PBM services to our clients consisting primarily of employers, insurance companies, unions, government employee groups, managed care organizations (MCOs) and other sponsors of health benefit plans and individuals throughout the United States.

Valuation of Specific CPT Codes

The Centers for Medicare and Medicaid Services (CMS) states that since the inception of the Physician Fee Schedule (PFS), a priority has been to revalue services regularly to assure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the calculations. In Table 46, CMS shows the impact of all its proposed changes on selected high volume procedures i.e., those most commonly furnished by a broad spectrum of specialties. Included in these is CPT Code 99213, for Office/Outpatient Visits for evaluation and management (E/M) of an established patient, for which the payment is proposed to increase by 1%. This will increase payment for non-facility visits from $73.30 to $74.01 or 71 cents per visit. While we appreciate the proposed increase and understand the many factors, including increased costs to beneficiaries and taxpayers, that must be taken into account in determining payment rates, we are concerned that this increase does not adequately reflect the current price for inputs or the increasing tasks involved. Labor costs alone are increasing at significantly more than 1% annually. In addition, consistent with goals and incentives in the Medicare program to move towards more cost effective care setting and care management, more health care services are being handled in an outpatient setting, resulting in further challenges to cover these and other

input costs at largely the same reimbursement rate. Accordingly, CVS Health respectfully recommends that CMS consider increasing the payment rate for this CPT code to at least reflect current inflation for medical services.

Improved Payment for the Professional Work of Care Management Services

CMS acknowledges stakeholder concerns about the challenge of accounting for all of the services and resources associated with the more extensive work that primary care physicians and other practitioners perform in planning and addressing the chronic care needs of particular subsets of Medicare beneficiaries. Specifically, CMS requests comments on ways to recognize the different resources involved in delivering care to these beneficiaries beyond the resources already incorporated in the existing Transitional Care Management (TCM) and the recently implemented Chronic Care Management (CCM) codes. CMS gives the example of add-on codes that might allow for the reporting of the additional time and intensity of the cognitive work often undertaken by primary care and other cognitive specialties in conjunction with an evaluation and management service. CVS Health supports the development of add-on codes for the additional resources involved in providing care to beneficiaries with chronic conditions. We agree that there are not only additional needs and considerations for different types of beneficiaries with chronic conditions, but also that these patients often require more intense effort, coordination and other services that are not necessarily adequately reflected in the existing codes. In developing any add-on codes for these purposes, CMS must keep in mind that many of these services are provided by nurse practitioners (NPs) and physician assistants (PAs) in the retail clinic setting. As we have stated previously, these providers play an integral role in providing services and coordinating care for patients with chronic care needs. This includes medication review, therapy consultation, counseling, and planning convenient access to available primary care resources as part of the overall strategy to manage their conditions. Accordingly, any add-on codes for addressing the additional resources involved in addressing the needs of patients with chronic conditions should be established in a manner that would allow them to be applied by NPs and PAs in a retail clinic setting.

Medicare Telehealth Services

CMS proposes to expand the coverage of telehealth services by adding several CPT codes related to telehealth services in an inpatient or observation setting and for end stage renal disease (ESRD) services for home dialysis. However, it rejected several requests to expand coverage of telehealth services in other situations, including for prolonged and online E/M services, CCM services and medication therapy management services provided by a pharmacist. While each is rejected for a specific, technical reason, such as that the description indicates that the service may be provided to a caregiver/guardian or that the service need not be performed face-to-face, the overall effect is to significantly limit the ability to use telehealth services in a retail clinic setting in non-rural areas.

While we appreciate the limited expansion of coverage for telehealth services and understand CMS's cautious approach, CVS Health remains concerned that the proposed rule takes too narrow a view of the benefits and utility of telehealth services, covering only a few of the many branches of telehealth services that have the potential to lower the cost of care without

sacrificing outcomes, and in a manner that is convenient and comfortable for patients. In keeping with the increased focus on health care quality and outcomes, private insurers and employers are today covering a much wider range of telehealth services across the country as compared to previous years. This is in stark contrast with the very limited coverage provided by Medicare. Given the advances in technology and proven ability of telehealth services to improve health and clinical access and reduce health costs, we urge CMS to expand its coverage of telehealth services to align with or exceed the coverage provided in the private market. This should include coverage of all E/M visits provided by telehealth. It would also allow the Medicare program to reap the full benefits of this technology in the same way as do other health insurance programs.

We also note that many beneficiaries in urban areas who would benefit significantly from the availability of telehealth services are still not eligible to receive them under Medicare. Many of these beneficiaries are unable to access health care services in person, whether as a result of physical limitations, personal circumstances or primary care physician shortages. The number of such beneficiaries is only likely to grow in coming years, exacerbating the situation. CVS Health continues to urge CMS to consider urban and suburban locations to be 'shortage' areas, and therefore eligible for covered telehealth services under Medicare.

Finally CVS Health requests that, as CMS expands its coverage of telehealth services, it clarify that NPs and PAs in retail clinic settings are eligible to bill telehealth CPT codes. The provision of telehealth services by these health care professionals is well within their licensed scope of care, and their telehealth services are currently reimbursed by private insurers. The reimbursement for the telehealth services of NPs and PAs should be commensurate with the reimbursement for the same services delivered during in-person care.

Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System

CVS Health supports CMS' efforts to align the reporting requirements in CMS' quality reporting programs to reduce burden on the eligible professionals (EPs) and group practices that participate in these programs. We also support the increased emphasis on reporting measures related to health outcomes, as well as resource use, patient experience of care, efficiency, and patient safety measures. As CMS notes, Congress has authorized the end of the PQRS in 2018 and the beginning of a new program, the Merit-based Incentive Payment System (MIPS), which will apply not only to physicians, but also to NPs, PAs and certain other non-physician practitioners.

CVS Health strongly supports the expansion of quality incentive programs to other health care providers and settings. We ask that in doing so, CMS includes NPs and PAs across all practice settings, including retail clinics, wherever possible. The role of non-physician health care providers operating in retail clinics and other more affordable and accessible health care settings is likely to grow in coming years as the health care landscape changes with health care reform. It is important that all health care providers have the same focus and incentives to improve health care quality and safety.

Payment for Biosimilar Biological Products

CMS' proposes to implement Section 3139 of the Affordable Care Act (ACA), which amends section 1847A of the Social Security Act, to define biosimilar and reference products, and to provide for Medicare payment of biosimilars using the average sales price (ASP) methodology. Specifically, CMS proposes that "products that rely on a common reference product's biologics license application" will be grouped into the same payment calculation. As CMS proposes, biosimilars sharing a common reference product would be processed under the same Healthcare Common Procedure Coding System (HCPCS) Level II J-Code. This means that their ASPs would be blended within the code they share.

CVS Health has concerns with the proposal to use a single ASP payment limit for biosimilar products that are assigned to a specific HCPCS code. CVS Health strongly discourages the grouping of non-interchangeable products into a single code for the purposes of reimbursement. While the availability of biosimilars in the United States promises to improve patient access to these new medicines in a cost-effective manner, the proposal to group all biosimilars under the same payment calculation and billing code, separate from the reference product, would discourage innovation and erect barriers to developing new biosimilar and interchangeable biologics, decreasing access to these important agents.

A reimbursement methodology that blends biosimilars into the same payment group/ASP would be very detrimental to the adoption of biosimilars for several reasons:

- ***Patient safety*** - Appropriately tracking product use when all products share a code places a significant administrative burden on providers who will need to develop systems within their practice to account for what product was administered to each patient. Therefore, in order to encourage physicians to prescribe and use physician-administered biologics for their patients, CMS should adopt a coding policy that is aligned with the FDA approval pathway. This would assign each biosimilar and the reference biologic their own J Code. Distinct codes would eliminate the safety and administrative barrier to biosimilar adoption otherwise faced by providers.

- ***Provider confusion*** - If multiple biosimilars to the same reference product share the same HCPCS code, providers may be confused as to the appropriate code to use and may not be confident that they will receive appropriate reimbursement for the product (biosimilar or reference) they prescribe and administer. This uncertainty is likely to be a disincentive to prescribing biosimilars. In addition, shared codes and volume-weighted payment across biosimilars will likely result in volatility in the ASP-based payment for these products quarter over quarter, increasing provider uncertainty and concern about whether they will be adequately reimbursed for administering any given biosimilar product. Because the reference biologic will retain its own code and product-specific payment rate, providers will have confidence that they will be adequately reimbursed for it, and will therefore be more likely to simply prescribe the reference product, for which the reimbursement is known. This unintended disincentive to prescribing biosimilars will undermine the otherwise significant cost savings that biosimilars cam bring to the health care system.

- ***Discourages biosimilar development*** **-** Failure to recognize the uniqueness of each biosimilar in the post-approval marketplace creates market uncertainty for biosimilar developers. The high-cost, lengthy development pathway for biosimilars makes this a high risk investment. High market uncertainty and failure to recognize the distinct nature of each biosimilar product in the same way as the FDA does will decrease investment in developing these types of products and, as a result, fewer biosimilars will come to market in the United States. Unlike the reference products, which retain their uniqueness and protection from direct price competition, the biosimilars will be viewed as interchangeable as a result of the "genericized" code/reimbursement methodology. Given the investment and resources required to bring any biologic to market, investors will likely opt to pursue innovator products following the full biologic license application process with the FDA rather than seeking to use the abbreviated pathway for biosimilars, or will abandon the pursuit all together.

- ***Difficult for Medicare Administrative Contractors (MACs) and other payers to write coverage policies*** **-** Medicare Administrative Contractors (MACs) would not be able to write coverage policies that limit use of each particular biosimilar to certain indications. Administrators would find it extremely difficult to write coverage policies describing when use of a particular biosimilar is clinically appropriate. The FDA clearly states that biosimilars are unique from each other and from their reference product. The proposal to assign all biosimilars for a common reference product the same billing code and payment is inconsistent with the approach of the FDA. This inconsistency creates challenges for payers implementing coverage policies for biosimilars. We anticipate that these products will also differ in their FDA-approved labeled indications, with the result that managing to on-label uses will be more difficult for payers as different biosimilars are treated as one for CMS reimbursement purposes.

CVS Health is also concerned that this reimbursement methodology is contrary to Congressional intent as reflected in the statutory construct or biosimilars created by ACA created a clear methodology for the payment of biosimilars, stating that the calculation for reimbursing biosimilars shall be made separately. This supports requiring that each biosimilar have its own unique payment rate and unique HCPCS code. The statutory language reflects the intent to encourage a vibrant biosimilars market, which can only occur if each biosimilar is assigned a unique billing code in the same way as the reference product.

In the proposed rule, CMS references the need to update previous requirements as stated in the 2011 PFS final rule, noting that "[a]t the time that the CY 2011 PFS final rule with comment period was published, it was not apparent how or when the new FDA abbreviated approval pathway would be implemented or when biosimilar products would be approved for marketing in the United States." While at present there is a single biosimilar product approved by the FDA for marketing, the abbreviated approval pathway is still not finalized. Notably, FDA still needs to decide on critical matters such as the terms for judging whether a biosimilar is interchangeable with its reference product and the naming convention under which new biosimilars will operate. Thus, consistent with CMS' stated reason for not proposing biosimilar reimbursement coding rules in 2011, we recommend that CMS continue that approach and not propose a reimbursement methodology until the FDA's biosimilar pathway is finalized, or at least until its most pressing

questions, such as its approach to interchangeability of biosimilar products, are decided and published in final form. CVS Health further recommends that if biosimilar biological product payment policy should go forward, CMS should adopt a coding policy that is aligned with the FDA approval pathway with each biosimilar and the reference biologic assigned to a specific HCPCS code.

CVS Health appreciates the opportunity to provide comments on this important proposed rule, and stands ready to work with CMS to improve access to care and outcomes for Medicare beneficiaries. If you have any questions, please feel free to contact me at (202) 772-3538 or Marissa.schlaifer@cvshealth.com.

Sincerely,

Marissa Schlaifer
Head of Policy
Government Affairs