American Autoimmune Related Diseases Association, Inc.

www.aarda.org

September 11, 2017

By Electronic Submission to www.regulations.gov

Seema Verma, Administrator
Centers for Medicare and Medicaid Services, Department of Health and Human Services
Attention: CMS–1676–P
P.O. Box 8016, Baltimore, MD 21244–8013

Re: **Comments on CMS-1676-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018, etc. — Proposed Rule (RIN 0938-AT02)**

Dear Ms. Verma:

The American Autoimmune Related Diseases Association (AARDA) appreciates the opportunity to comment on the Medicare Proposed Rule addressing Revisions to Payment Policies Under the Physician Fee Schedule (PFS) and Other Revisions to Part B for CY 2018 (Proposed Rule).[1] Specifically, we write in response to the Proposed Rule's solicitation of public comments on biosimilars (Section III.D).[2]

AARDA is the only national nonprofit organization dedicated to raising awareness and addressing the problem of autoimmune disease, which affects more than 50 million Americans and is the second-leading cause of chronic disease in the U.S. AARDA is also the founder and facilitator of the National Coalition of Autoimmune Patient Groups (NCAPG), a coalition of 38 patient advocate organizations representing numerous autoimmune diseases. The mission of the NCAPG is to consolidate the voice of autoimmune disease patients and to promote increased education, awareness, and research into all aspects of autoimmune diseases through a collaborative approach.

AARDA previously has addressed the biosimilars payment policy under the Medicare program, in response to the Final Rule with Comment Period titled "Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016" (Final Rule), published by the Centers for Medicare and Medicaid Services (CMS) on November 16, 2015.[3] In those comments, which we incorporate here by reference,[4] AARDA expressed hope and excitement regarding the potential benefits that biosimilars can bring to patients in terms of increasing access to therapies. However, we also emphasized and discussed our significant concerns regarding the CMS policy for the payment of biosimilars under Medicare Part B as articulated in that rule. In light of those concerns as communicated at that time by AARDA and other stakeholders, and given our continuing concerns with the currently effective payment policy for biosimilars and that policy's impact on biosimilars innovation, access, and competition, we greatly appreciate the agency's work in reviewing and potentially revising this policy.

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[1] 82 Fed. Reg. 33,950 (July 21, 2017).

[2] 82 Fed. Reg. at 33,951 & 34,090–91 (addressing and soliciting comments on "*Payment for Biosimilar Biological Products Under Section 1847A of the [Social Security] Act*").

[3] 80 Fed. Reg. 70,886 (Nov. 16, 2015).

[4] *See* AARDA Comments on CMS–1631–FC (Dec. 29, 2015), attached as an Appendix to these comments.

On behalf of the tens of millions of patients in the United States with autoimmune diseases and their families, and in furtherance of AARDA's deep commitment to ensuring adequate access to appropriate care for patients with autoimmune diseases, we offer the following comments to the Proposed Rule and urge CMS to implement changes to the current Part B payment policy for biosimilar biological products.

Overview. Individuals with autoimmune diseases face significant health challenges, often requiring lengthy evaluation and referral processes involving many specialists as well as therapeutic trial-and-error in order to diagnose, treat, and manage their symptoms. Many autoimmune patients also rely on medications that are covered and reimbursed under Medicare Part B, including biologics. As a result, policies affecting coverage and payment for biologics, including biosimilars, have a significant impact on autoimmune patients and their families. We and our members have experienced firsthand the impact of biologics in improving and extending the lives of autoimmune patients with diseases such as rheumatoid arthritis, lupus, Crohn's, multiple sclerosis, Sjögren's syndrome, relapsing polychondritis, and others. We are excited about the potential benefits that biosimilars can bring to patients in terms of increasing access to therapies.

We have significant concerns, however, about CMS' current policy for the payment of biosimilars under Medicare Part B. We believe that both the statute and a variety of important policies underscore the need for CMS to issue separate Healthcare Common Procedure Coding System (HCPCS) codes for each biologic product—biosimilars as well as reference products. In part, this is necessary to ensure that each biologic product, including each biosimilar, has a separate average sales price (ASP)-based reimbursement, as the statute requires. The policy that we support is also necessary to protect patient safety and to provide appropriate incentives for the biosimilars market, as intended by Congress, and as CMS appropriately identifies as a priority in the Proposed Rule.[5] In addition, the policy that we support is consistent with CMS precedent that recognizes and treats biosimilars as single source drugs, not as multiple source drugs.

Importantly, the policy that we support also provides workable solutions for key issues noted by CMS in the Proposed Rule, including, for example, how to address "the innate differences in biological products" and how to reflect such differences in Medicare payment policy, such as instances of "biosimilars that are licensed for fewer than all indications for which the reference product is licensed or situations where different biosimilars may be licensed for different subsets of indications for which the reference product is licensed."[6] These issues underscore the fact that biosimilars—though "similar"—are each distinct products. Accordingly, they should be identified with unique HCPCS codes and reimbursed accordingly under Medicare's payment policy, as discussed further below.

Statutory Requirement. We strongly oppose CMS' current policy to reimburse multiple biosimilars associated with a particular reference product using a single HCPCS code because we believe it is contrary to the statute. Section 3139 of the Affordable Care Act (ACA) amended section 1847A of the Social Security Act (SSA) to define a biosimilar biological product and a reference biological product, and to provide for Medicare payment of biosimilar biological products under the ASP methodology. Specifically, the law requires that reimbursement for a biosimilar biological product be the ASP of each biosimilar and its National Drug Codes (NDCs) plus 6% of the ASP of the reference product.[7] Pursuant to this language, CMS is required to ensure that each biosimilar has a separate ASP-based reimbursement.

Despite this clear statutory language, CMS in 2015 finalized its proposal to include all biosimilars of a particular reference product under the same HCPCS code, meaning that reimbursement under Medicare Part B, as of January 1, 2016, is calculated as a weighted average of those biosimilars' ASP. We strongly believe that this is inconsistent with the plain language of the statute, and we urge CMS to revise this policy.

[5] 82 Fed. Reg. at 34,090–91.

[6] *Id.* at 34,091.

[7] ACA § 3139, amending SSA § 1847A; *see also* 42 C.F.R. § 1395w-3a(b)(8).

CMS appeared to argue in the 2015 Final Rule that its policy is consistent with the statute because of the reference in the biosimilars payment provision (SSA § 1847A(b)(8)) to the "methodology described under paragraph (6)" of the ASP statute—specifically, the methodology described under SSA § 1847A(b)(6) that relates to the "[u]se of volume-weighted average sales prices in calculation of average sales price."[8] CMS also recognized, however, that the ASP statute additionally references the methodology applied under section 1847(b)(6) in connection with the payment amount for single source drugs and biologicals that are furnished on or after April 1, 2008 (SSA § 1847A(b)(4)). Nevertheless, CMS indicated in 2015 its belief that this statutory reference in connection with single source drugs is somehow different from the similar reference in connection with multiple source drugs and biosimilars.[9] As noted in our prior comments, we do not agree with that reasoning as reflected in the 2015 Final Rule.

The purpose of the reference to paragraph (6) is the same in connection with biosimilars as it was in connection with single source drugs and biologicals, originally. Any product—including a single source drug or biological, and including a biosimilar or reference product—may have multiple National Drug Codes (NDCs) associated with it. The reference to paragraph (6) in both the single source and biosimilars payment clauses under section 1847A(b) simply enables CMS to calculate a separate ASP for ***each, unique*** single source drug, biological, or biosimilar. It is true that paragraph (6) under section 1847A(b) refers to "multiple source drug billing and payment code[s]"—but that is merely a reference back to other sections of the statute, which created a special rule for drugs and biologicals that were in the same, multiple source payment code as of October 1, 2003.[10] As reviewing courts have cautioned, the plain language of a statute must be addressed in context,[11] and CMS' position as articulated in the 2015 Final Rule negates both (1) the context of the presence of this language in the "single source" clause (section 1847A(b)(4)) and (2) the special rule found at section 1847A(c)(6)(C)(ii).

Indeed, CMS' reading of the statute effectively attempts to negate Congress' decision not to include biosimilars in the "multiple source drug" definition, but to separately define these products in their own, quite separate and distinct statutory section. This fact underscores that Congress defined biosimilars *in juxtaposition to* multiple source drugs. CMS' reading under the 2015 Final Rule not only negates critically important context, but it also fails to apply the plain language of the statutory words selected by Congress.

Accordingly, we do not believe that the statute supports the distinction that CMS previously articulated in support of the current payment policy, and we do not believe that the statute provides the discretion that CMS has suggested it has to group biosimilars of the same reference product into a single HCPCS code.

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[8] 80 Fed. Reg. at 71,097–98.

[9] *See id.* at 71,098 ("Section 1847A(b)(6)(A) of the Act states that it applies to all drug products included within the same multiple source drug billing and payment code before setting forth the methodology for determining a volume weighted average sales price for multiple source drugs. The statute also specifies the use of this methodology for determining the average sales prices for single source drugs (under section 1847A(b)(4) of the Act) and biosimilars (under section 1847A(b)(8) of the Act). However, sections 1847A(b)(4) and 1847A(b)(8) of the Act differ in one significant respect; namely, that only section 1847A(b)(8) of the Act includes language that directs the payment determination in paragraph (b)(6) to be carried out in the same manner as paragraph (b)(6) is applied to drugs that are described in paragraph (b)(6)."). We disagree with the difference cited here by CMS, as section 1847A(b)(4)—relating to single source drugs—plainly states that the ASP amount "for a single source drug or biological" is "*determined using . . . the methodology applies under paragraph (6) for single source drugs or biologicals* furnished on or after April 1, 2008, for all National Drug Codes assigned to such drug or biological product" (emphasis added).

[10] *See* SSA § 1847A(c)(6)(C)(ii) (statutory definition of "multiple source drug" and relevant exception for "single source drugs or biologicals that [were] within the same billing and payment code as of October 1, 2003"); *see also* SSA § 1847A(b)(1)(A).

[11] Under *Chevron U.S.A. Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984), a Court "'determin[es] the plainness or ambiguity of statutory language'" only after examining "'the language itself, the specific context in which that language is used, and the broader context of the statute as a whole.'" *United States v. Wilson*, 290 F.3d 347, 353 (D.C. Cir. 2002) (quoting *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 241 (1989)).

Thus, we believe the policy must be updated to provide that each biosimilar biological product will receive its own HCPCS code and will be reimbursed, as the statute requires, at an amount that is the sum of the ASP of each biosimilar product and its NDCs plus 6% of the applicable reference product's ASP.

Consistency with CMS Precedent. The plain language reading of the statute that we have articulated above is also consistent with CMS' own precedent, which treats biosimilars as single source drugs in other contexts. For example, CMS has stated that, for purposes of the Medicaid Drug Rebate Program, biosimilars will be treated as single source drugs.[12] Treating biosimilars as multiple source drugs in some contexts but as single source drugs in others is inconsistent and arbitrary, and is likely to cause significant confusion and errors in billing and payment. It is appropriate to treat biosimilars as single source drugs because, although biosimilar products may be "similar" to each other and/or to the reference product, they are—by definition—*not* identical or equivalent. As CMS is aware, the use of volume-weighted ASPs is limited, by statute, to multiple source drugs.[13] Because biosimilars are not multiple source drugs, the current payment policy is inconsistent with both the statute and with CMS precedent.

Tracking, Pharmacovigilance, and Patient Safety. In addition, we—along with many other stakeholders—fear that the current biosimilars payment policy under Medicare Part B, if not updated as we suggest, will continue to impair and undermine important tracking and pharmacovigilance efforts. That, in turn, will jeopardize patient safety. Coding all biosimilars of a particular reference product together inevitably creates patient safety risks and situations of errors in identifying and prescribing the correct biosimilar, as well as complications in tracking biosimilars for adverse events and other safety-related issues. Although CMS acknowledged these concerns in the 2015 Final Rule, the agency did not, in our view, fully appreciate or adequately address them. Patient safety is of paramount importance. We believe CMS should do everything within its power to put patient safety first. The Medicare program exists for the benefit of its beneficiaries, and CMS owes a fiduciary responsibility to those beneficiaries.

These issues are critically important because, as noted, "similar" products, by definition, are *not identical*, and any dissimilarity can result in significant differences for patients in terms of efficacy and safety. Given the complex, chronic, and often life-threatening nature of autoimmune disorders, cancers, primary immune deficiencies, and a number of other rare diseases, as well as how they interact with other conditions that a patient might have or other medications that a patient may need, a clear, transparent coding system is essential. Patients and prescribers must be able to understand readily which product is being prescribed and to track cleanly patients' reactions and responses to that particular therapy. Use of the same HCPCS code for multiple different biosimilar biological products also could result in "pooled" data that clouds clinical outcomes assessments and can be dangerous to patients.

In the 2015 Final Rule, CMS acknowledged these concerns relating to tracking and pharmacovigilance, but stated that "[p]harmacovigilance and the postmarketing assessment of the safety and efficacy of drugs and biologicals are frequently conducted by the FDA," and asserted that "[t]he FDA's determinations are outside the scope of this rule."[14] Nevertheless, CMS also acknowledged that FDA policies (and a number of other critically important issues, such as "coverage policies, clinical decision making, and the clinical use of biosimilars") "overlap with" CMS payment policy.[15] Accordingly, we believe it is clear that issues of tracking and pharmacovigilance are within the scope of the CMS payment policy for biosimilars and should be considered as CMS reviews and, we hope, revises the current policy.

[12] Medicaid Drug Rebate Program Manufacturer Release 92 and State Release 169 (Mar. 30, 2015).

[13] SSA § 1847A; 42 C.F.R. § 1395w-3a(b)(6).

[14] 80 Fed. Reg. at 71,101.

[15] *Id.* at 71,097.

Notably, CMS has recognized the importance of tracking and pharmacovigilance in connection with its biosimilars policy, such as by stating in the 2015 Final Rule that the agency "will provide guidance on mechanisms for tracking drug use through information on claims in the near future" and is "developing an approach for using manufacturer-specific modifiers on claims to assist with pharmacovigilance."[16] We note that such guidance would not be necessary if CMS acted consistently with the statute and its precedent in recognizing that each biosimilar should receive a unique HCPCS code and its own separate ASP-based reimbursement as prescribed by Congress. In that vein, we note the significant additional risk of modifier misuse and confusion, as compared to the selection of an incorrect HCPCS code. The problem of mistakes and errors with modifier assignments has long been a substantial challenge, and we continue to urge CMS to be mindful of those issues and that history. Further, as noted above, issuing separate HCPCS codes also appropriately addresses the "innate differences" between and among different biosimilar biological products, as well as differences in the indications or subsets of indications for which different biosimilars may be approved. Thus, the policy we suggest is more efficient and less burdensome, in addition to being consistent with the statute.

Preserving Independent Clinical Decision Making and Incentives for Innovation. In addition to issues of "prescriber confusion" that can result from the grouping of multiple biosimilar biological products into a single HCPCS code, the current policy also has an impact—even absent any prescriber confusion—on prescriber decision making and payer coverage policies. Moreover, we fear that the current payment policy disincentivizes the development of new biosimilars. Innovators have little incentive to invest in a new or improved biosimilar if they know that reimbursement will be a weighted average of all biosimilars associated with a particular reference product—and this is especially true given the statutory requirement that the reference product retain its own separate code and reimbursement methodology. Without adequate incentives for innovation, patient access will be impaired, and the promises of biosimilars to bring new and more affordable treatments to the healthcare system and to patients will not be realized. In addition, the reality is that inadequate reimbursement for a product or class of products inevitably influences clinical decision making; this has a significant impact on patients, on the Medicare program, and on the biosimilars market. We are deeply concerned that CMS' current policy often may lead providers to prescribe based on reimbursement considerations and not based on clinical needs.

AARDA strongly believes in the importance of biosimilar development, as we believe that it holds the promise for patients with autoimmune diseases who currently have very limited treatment options. Our members who rely on biologics know all too well that different treatments—even if "similar"—can cause varied reactions for different patients, particularly those with complex diseases. What works for one patient with a complex condition often will not work for another patient with the same disease.[17] We believe that our collective perspective as patient advocates is important for CMS to consider, consistent with our shared goal to advance high quality, patient-centered care that both promotes innovation and protects the public health. Thus, it is critical that a number of treatment options be available to ensure these patients can identify a treatment that works for them, and that CMS payment policies support, rather than undermine, this goal.

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[16] *Id.* at 71,101.

[17] *See, e.g.*, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), "Handout on Health: Systemic Lupus Erythematosus," http://www.niams.nih.gov/HEALTH_INFO/LUPUS/DEFAULT.ASP#Lupus_6 (May 2013) (noting that "lupus is different in different people and is characterized by autoimmunity in various systems of the body," and that "[m]any symptoms can come and go overtime," such that a treatment plan must be based on the patient's specific symptoms and characteristics, and "tailored to the individual's needs"); NIAMS, "Handout on Health: Rheumatoid Arthritis," http://www.niams.nih.gov/health_info/Rheumatic_Disease/default.asp#ra_10 (April 2013) (describing various treatments for rheumatoid arthritis and how they may vary from person to person); Am. College of Rheumatology, "Sjögren's Syndrome," http://www.rheumatology.org/Practice/Clinical/Patients/Diseases_And_Conditions/Sj%C3%B6gren_s_Syndrome/ (noting that "[s]ymptoms vary in type and intensity" and describing several types of treatments that may work in "some" patients but not others, depending on the patient's specific characteristics and symptoms).

Additional Support. We note, as CMS recognized in the 2015 Final Rule and in the current Proposed Rule, that we are not alone in our view that the agency's is contrary to statute.[18] We understand that a number of physician groups, including Alliance for Patient Access, American Association of Clinical Endocrinologists, American College of Rheumatology, American Gastroenterological Association, Biologics Prescribers Collaborative and Coalition of State Rheumatology Organizations, previously wrote to lawmakers asking them to act so that CMS does not move forward with this biosimilar reimbursement policy. We understand that Members of Congress also have written to the agency to articulate this concern. We urge CMS to correct its position quickly in order to ensure consistency with the statute, patient safety, and appropriate incentives for biosimilars innovation and independent clinical decision making.

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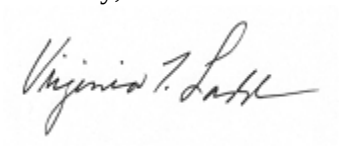
Thank you again for your consideration of our comments, and we look forward to continuing to work with you on these important issues.

Sincerely,



Virginia T. Ladd
President/Executive Director
American Autoimmune Related Diseases Association

[18] *See* 80 Fed. Reg. at 71,097; 82 Fed. Reg. at 34,090.

American Autoimmune Related Diseases Association, Inc.

www.aarda.org

December 29, 2015

By Electronic Submission to www.regulations.gov

Andy Slavitt, Acting Administrator
Centers for Medicare and Medicaid Services, Department of Health and Human Services
Attn: CMS–1631–FC
P.O. Box 8013, Baltimore, MD 21244–1850

Re: **Comments on CMS-1631-FC: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 — Final Rule with Comment Period (RIN 0938-AS40)**

Dear Mr. Slavitt:

The American Autoimmune Related Diseases Association (AARDA) appreciates the opportunity to comment on the Medicare Final Rule with Comment Period titled "Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016" (Final Rule), published by the Centers for Medicare and Medicaid Services (CMS) on November 16, 2015.[1] AARDA is the only national nonprofit organization dedicated to raising awareness and addressing the problem of autoimmunity, which affects more than 50 million Americans and is the second-leading cause of chronic disease in the U.S.

AARDA is also the founder and facilitator of the National Coalition of Autoimmune Patient Groups (NCAPG), a coalition of 38 patient advocate organizations representing numerous autoimmune diseases. The mission of the NCAPG is to consolidate the voice of autoimmune disease patients and to promote increased education, awareness, and research into all aspects of autoimmune diseases through a collaborative approach.

Individuals with autoimmune diseases face significant health challenges, often requiring lengthy evaluation and referral processes involving many specialists as well as therapeutic trial-and-error in order to diagnose, treat, and manage their symptoms. Many autoimmune patients also rely on medications that are covered and reimbursed under Medicare Part B, including biologics. As a result, policies affecting coverage and payment for biologics, including biosimilars, have a significant impact on autoimmune patients and their families. We and our members have experienced firsthand the impact of biologics in improving and extending the lives of autoimmune patients with diseases such as rheumatoid arthritis, lupus, Crohn's, multiple sclerosis, Sjögren's syndrome, relapsing polychondritis, and others. We are excited about the potential benefits that biosimilars can bring to patients in terms of increasing access to therapies. On behalf of these individuals and their families, and in light of AARDA's deep commitment to ensuring adequate access to appropriate care for patients with autoimmune diseases, we offer the following comments to the Final Rule.[2]

[1] 80 Fed. Reg. 70,886 (Nov. 16, 2015).

[2] We note that CMS has specified certain areas of the Final Rule that the Agency considers to be "open for comment" (80 Fed. Reg. at 70,886 & 70,887). Although the biosimilars payment policy is not expressly listed, CMS makes clear that this Final Rule is a Final Rule *with Comment Period*, such that it is open for additional stakeholder feedback. Further, CMS indicates in the Final Rule that the Agency will continue to evaluate biosimilars payment policy under Medicare Part B as the market develops, and expressly states that CMS "agree[s] with commenters who support future refinements to policy as needed based on actual experience with this new segment of the market." 80 Fed. Reg. at

Specifically, we have significant concerns about CMS' policy for the payment of biosimilars under Medicare Part B as articulated in the Final Rule. We believe that both the statute and a variety of important policies underscore the need for CMS to issue separate Healthcare Common Procedure Coding System (HCPCS) codes for each biologic product—biosimilars as well as reference products. In part, this is necessary to ensure that each biologic product, including each biosimilar, has a separate average sales price (ASP)-based reimbursement, as the statute requires. The policy that we support is also necessary to protect patient safety and to provide appropriate incentives for the biosimilars market, as intended by Congress. In addition, the policy that we support is consistent with CMS precedent to date that recognizes and treats biosimilars as single source drugs, not as multiple source drugs. We discuss these comments and concerns further below.

Statutory Requirement. We strongly oppose CMS' policy to reimburse multiple biosimilars associated with a particular reference product using a single HCPCS code because we believe it is contrary to the statute. Section 3139 of the Affordable Care Act (ACA) amended section 1847A of the Social Security Act (SSA) to define a biosimilar biological product and a reference biological product, and to provide for Medicare payment of biosimilar biological products under the ASP methodology. Specifically, the law requires that reimbursement for a biosimilar biological product be the ASP of each biosimilar and its National Drug Codes (NDCs) plus 6% of the ASP of the reference product.[3] Pursuant to this language, CMS is required to ensure that each biosimilar has a separate ASP-based reimbursement.

Despite this clear statutory language, in the Final Rule, CMS has finalized its proposal to include all biosimilars of a particular reference product under the same HCPCS code, meaning that reimbursement under Medicare Part B will be a weighted average of those biosimilars' ASP. We strongly believe that this is inconsistent with the plain language of the statute, and we urge CMS to reconsider and revise this policy.

CMS appears to argue in the Final Rule that its policy is consistent with the statute because of the reference in the biosimilars payment provision (SSA § 1847A(b)(8)) to the "methodology described under paragraph (6)" of the ASP statute—specifically, the methodology described under SSA § 1847A(b)(6) that relates to the "[u]se of volume-weighted average sales prices in calculation of average sales price."[4] CMS recognizes, however, that the ASP statute also references the methodology applied under section 1847(b)(6) in connection with the payment amount for single source drugs and biologicals that are furnished on or after April 1, 2008 (SSA § 1847A(b)(4)); nevertheless, CMS states its belief that this statutory reference in connection with single source drugs is somehow different from the similar reference in connection with multiple source drugs and biosimilars.[5] We do not agree with CMS' reasoning on this point.

71,101. Accordingly, these comments are within the scope of the comment period provided for the Final Rule and are properly considered by CMS as it continues to evaluate, assess, and refine its payment policy for biosimilars under Medicare Part B, including the potential—cited by CMS in the Final Rule—that CMS may, under the revised regulation text, "separate[e] some, or all, of a group of biosimilars for payment (and . . . creat[e] . . . one or more separate HCPCS codes) should a program need arise to do so." *Id.* at 71,098. As described in these comments, we believe, based on our experience with biologics, including biosimilars, that such a program need exists and will only increase going forward.

[3] ACA § 3139, amending SSA § 1847A; *see also* 42 C.F.R. § 1395w-3a(b)(8).

[4] 80 Fed. Reg. at 71,097–98.

[5] *See id.* at 71,098 ("Section 1847A(b)(6)(A) of the Act states that it applies to all drug products included within the same multiple source drug billing and payment code before setting forth the methodology for determining a volume weighted average sales price for multiple source drugs. The statute also specifies the use of this methodology for determining the average sales prices for single source drugs (under section 1847A(b)(4) of the Act) and biosimilars (under section 1847A(b)(8) of the Act). However, sections 1847A(b)(4) and 1847A(b)(8) of the Act differ in one significant respect; namely, that only section 1847A(b)(8) of the Act includes language that directs the payment determination in paragraph (b)(6) to be carried out in the same manner as paragraph (b)(6) is applied to drugs that are described in paragraph (b)(6)."). We disagree with the difference cited here by CMS, as section 1847A(b)(4)—relating to single source drugs—plainly states that the ASP amount "for a single source drug or biological" is "*determined using*

The purpose of the reference to paragraph (6) is the same in connection with biosimilars as it was in connection with single source drugs and biologicals, originally. Any product—including a single source drug or biological, and including a biosimilar or reference product—may have multiple NDCs associated with it. The reference to paragraph (6) in both the single source and biosimilars payment clauses under section 1847A(b) simply enables CMS to calculate a separate ASP for ***each, unique*** single source drug, biological, or biosimilar. It is true that paragraph (6) under section 1847A(b) refers to "multiple source drug billing and payment code[s]"—but that is merely a reference back to other sections of the statute, which created a special rule for drugs and biologicals that were in the same, multiple source payment code as of October 1, 2003.[6] As reviewing courts have cautioned, the plain language of a statute must be addressed in context,[7] and CMS' position as articulated in the Final Rule negates both (1) the context of the presence of this language in the "single source" clause (section 1847A(b)(4)) and (2) the special rule found at section 1847A(c)(6)(C)(ii).

Indeed, CMS' reading of the statute effectively attempts to negate Congress' decision not to include biosimilars in the "multiple source drug" definition, but to separately define these products in their own, quite separate and distinct statutory section. This fact underscores that Congress defined biosimilars *in juxtaposition to* multiple source drugs. CMS' reading not only negates critically important context, but it also fails to apply the plain language of the statutory words selected by Congress.

Accordingly, we do not believe that the statute supports the distinction that CMS articulates, and we do not believe that the statute provides the discretion that CMS believes it has to group biosimilars of the same reference product into a single HCPCS code. Thus, we believe the policy must be updated to provide that each biosimilar biological product will receive its own HCPCS code and will be reimbursed, as the statute requires, at an amount that is the sum of the ASP of each biosimilar product and its NDCs plus 6% of the applicable reference product's ASP.

Consistency with CMS Precedent. The plain language reading of the statute that we have articulated above is also consistent with CMS' own precedent, which treats biosimilars as single source drugs in other contexts. For example, CMS has stated that, for purposes of the Medicaid Drug Rebate Program, biosimilars will be treated as single source drugs.[8] Treating biosimilars as multiple source drugs in some contexts but as single source drugs in others is inconsistent and arbitrary, and is likely to cause significant confusion and errors in billing and payment. It is appropriate to treat biosimilars as single source drugs because, although biosimilar products may be "similar" to each other and/or to the reference product, they are—by definition—*not* identical or equivalent. As CMS is aware, the use of volume-weighted ASPs is limited, by statute, to multiple source drugs.[9] Because biosimilars are not multiple source drugs, the payment policy articulated in the Final Rule is inconsistent with both the statute and with CMS precedent.

. . . *the methodology applies under paragraph (6) for single source drugs or biologicals* furnished on or after April 1, 2008, for all National Drug Codes assigned to such drug or biological product" (emphasis added).

[6] *See* SSA § 1847A(c)(6)(C)(ii) (statutory definition of "multiple source drug" and relevant exception for "single source drugs or biologicals that [were] within the same billing and payment code as of October 1, 2003"); *see also* SSA § 1847A(b)(1)(A).

[7] Under *Chevron U.S.A. Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984), a Court "'determin[es] the plainness or ambiguity of statutory language'" only after examining "'the language itself, the specific context in which that language is used, and the broader context of the statute as a whole.'" *United States v. Wilson*, 290 F.3d 347, 353 (D.C. Cir. 2002) (quoting *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 241 (1989)).

[8] Medicaid Drug Rebate Program Manufacturer Release 92 and State Release 169 (Mar. 30, 2015).

[9] SSA § 1847A; 42 C.F.R. § 1395w-3a(b)(6).

Tracking, Pharmacovigilance, and Patient Safety. In addition, we fear that the biosimilars payment policy under Medicare Part B, as articulated by CMS in the Final Rule, will impair and undermine important tracking and pharmacovigilance efforts; that, in turn, will jeopardize patient safety. If all biosimilars of a particular reference product are coded together, there could be errors in identifying and prescribing the correct biosimilar, as well as complications in tracking biosimilars for adverse events and other safety-related issues. CMS acknowledges these concerns in the Final Rule but, in our view, fails to fully appreciate them. The Agency should do everything (within its power) to put patient safety first. The Medicare program exists for the benefit of its beneficiaries, and CMS owes a fiduciary responsibility to those beneficiaries.

These issues are critically important because, as noted, "similar" products, by definition, are *not identical*, and any dissimilarity can result in significant differences for patients in terms of efficacy and safety. Given the complex, chronic, and often life-threatening nature of autoimmune disorders, cancers, primary immune deficiencies, and a number of other rare diseases, as well as how they interact with other conditions that a patient might have or other medications that a patient may need, a clear, transparent coding system is essential. Patients and prescribers must be able to understand readily which product is being prescribed and to track cleanly patients' reactions and responses to that particular therapy. Use of the same HCPCS code for multiple different biosimilar biological products also could result in "pooled" data that clouds clinical outcomes assessments and can be dangerous to patients.

In the Final Rule, CMS acknowledges these concerns relating to tracking and pharmacovigilance, but states that "[p]harmacovigilance and the postmarketing assessment of the safety and efficacy of drugs and biologicals are frequently conducted by the FDA," and asserts that "[t]he FDA's determinations are outside the scope of this rule."[10] Nevertheless, CMS also acknowledges in the Final Rule that FDA policies (and a number of other critically important issues, such as "coverage policies, clinical decision making, and the clinical use of biosimilars") "overlap with" CMS payment policy.[11]

Accordingly, we respectfully disagree with CMS that issues of tracking and pharmacovigilance are outside the scope of this Final Rule or of CMS payment policy. Indeed, CMS itself concedes as much in stating that CMS "will provide guidance on mechanisms for tracking drug use through information on claims in the near future."[12] Specifically, CMS adds, the Agency is "developing an approach for using manufacturer-specific modifiers on claims to assist with pharmacovigilance."[13] We note that such guidance would not be necessary if CMS acted consistently with the statute and its precedent in recognizing that each biosimilar should receive a unique HCPCS code and its own separate ASP-based reimbursement as prescribed by Congress. In that vein, we note the significant additional risk of modifier misuse and confusion, as compared to the selection of an incorrect HCPCS code. The problem of mistakes and errors with modifier assignments has long been a substantial challenge, and we urge CMS to be mindful of those issues and that history.

Preserving Independent Clinical Decision Making and Incentives for Innovation. In addition, we are concerned that, even if provider "confusion" does not result from the grouping of multiple biosimilar biological products into a single HCPCS code, this policy has significant potential to influence prescriber decision making and payer coverage policies. Moreover, we fear that the payment policy articulated in the Final Rule will disincentivize the development of new biosimilars. Manufacturers will have little incentive to invest in a new or improved biosimilar if they know that reimbursement will be a weighted average of all biosimilars associated with a particular reference product—and this is especially true given the statutory requirement that the reference product retain its own separate code and reimbursement methodology. Without adequate incentives for innovation, patient access will be impaired, and the promises of biosimilars

[10] 80 Fed. Reg. at 71,101.

[11] *Id.* at 71,097.

[12] *Id.* at 71,101.

[13] *Id.*

to bring new and more affordable treatments to the healthcare system and to patients will not be realized. Moreover, if adequate reimbursement is not provided for biosimilar products, this will inevitably influence clinical decision making, causing a significant impact on patients, on the Medicare program, and on the biosimilars market. We are deeply concerned that CMS' policy, as articulated in the Final Rule, may force providers to prescribe based on reimbursement considerations and not based on clinical needs.

AARDA strongly believes in the importance of biosimilar development, as we believe that it holds the promise for patients with autoimmune diseases who currently have very limited treatment options. Our members who rely on biologics know all too well that different treatments—even if "similar"—can cause varied reactions for different patients, particularly those with complex diseases. What works for one patient with a complex condition often will not work for another patient with the same disease.[14] We believe that our collective perspective as patient advocates is important for CMS to consider, consistent with our shared goal to advance high quality, patient-centered care that both promotes innovation and protects the public health. Thus, it is critical that a number of treatment options be available to ensure these patients can identify a treatment that works for them, and that CMS payment policies support, rather than undermine, this goal.

Additional Support. We note, as CMS recognizes,[15] that we are not alone in our view that the Agency's policy as articulated in the Final Rule is contrary to statute. We understand that a number of physician groups, including Alliance for Patient Access, American Association of Clinical Endocrinologists, American College of Rheumatology, American Gastroenterological Association, Biologics Prescribers Collaborative and Coalition of State Rheumatology Organizations, have written to Senator Hatch (R-UT) and other lawmakers asking them to act so that CMS does not move forward with this biosimilar reimbursement policy. We understand that Members of Congress have written to the Agency to articulate this concern, as well. We urge CMS to correct its position quickly in order to ensure consistency with the statute, patient safety, and appropriate incentives for biosimilars innovation and independent clinical decision making.

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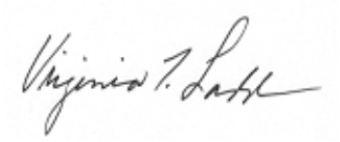
Thank you again for your consideration of our comments, and we look forward to continuing to work with you on these important issues.

Sincerely,



Virginia T. Ladd
President/Executive Director
American Autoimmune Related Diseases Association

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[14] *See, e.g.*, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), "Handout on Health: Systemic Lupus Erythematosus," http://www.niams.nih.gov/HEALTH_INFO/LUPUS/DEFAULT.ASP#Lupus_6 (May 2013) (noting that "lupus is different in different people and is characterized by autoimmunity in various systems of the body," and that "[m]any symptoms can come and go overtime," such that a treatment plan must be based on the patient's specific symptoms and characteristics, and "tailored to the individual's needs"); NIAMS, "Handout on Health: Rheumatoid Arthritis," http://www.niams.nih.gov/health_info/Rheumatic_Disease/default.asp#ra_10 (April 2013) (describing various treatments for rheumatoid arthritis and how they may vary from person to person); Am. College of Rheumatology, "Sjögren's Syndrome," http://www.rheumatology.org/Practice/Clinical/Patients/Diseases_And_Conditions/Sj%C3%B6gren_s_Syndrome/ (noting that "[s]ymptoms vary in type and intensity" and describing several types of treatments that may work in "some" patients but not others, depending on the patient's specific characteristics and symptoms).

[15] 80 Fed. Reg. at 71,097.