

PROTECTING ACCESS TO DIABETES SUPPLIES ACT OF
 2017

DECEMBER 6, 2017.—Committed to the Committee of the Whole House on the State
 of the Union and ordered to be printed

Mr. WALDEN, from the Committee on Energy and Commerce,
 submitted the following

R E P O R T

[To accompany H.R. 3271]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 3271) to amend title XVIII of the Social Security Act in order to strengthen rules in case of competition for diabetic testing strips, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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The amendment is as follows:
 Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “Protecting Access to Diabetes Supplies Act of 2017”.

SEC. 2. STRENGTHENING RULES IN CASE OF COMPETITION FOR DIABETIC TESTING STRIPS.**(a) SPECIAL RULE IN CASE OF COMPETITION FOR DIABETIC TESTING STRIPS.—**

(1) **IN GENERAL.**—Paragraph (10) of section 1847(b) of the Social Security Act (42 U.S.C. 1395w–3(b)) is amended—

(A) in subparagraph (A), by striking the second sentence and inserting the following new sentence: “With respect to bids to furnish such types of products on or after January 1, 2019, the volume for such types of products shall be determined by the Secretary through the use of multiple sources of data (from mail order and non-mail order Medicare markets), including market-based data measuring sales of diabetic testing strip products that are not exclusively sold by a single retailer from such markets.”; and

(B) by adding at the end the following new subparagraphs:

“(C) **DEMONSTRATION OF ABILITY TO FURNISH TYPES OF DIABETIC TESTING STRIP PRODUCTS.**—With respect to bids to furnish diabetic testing strip products on or after January 1, 2019, under the program described in subparagraph (A), the Secretary shall reject a bid submitted by an entity if the entity does not attest to the Secretary and demonstrate, through letters of intent with manufacturers, wholesalers, or other suppliers, or other evidence as the Secretary may specify, that the entity has the ability to obtain an inventory of the types and quantities of diabetic testing strip products that will allow the entity to furnish such products in a manner consistent with its bid.

“(D) **USE OF UNLISTED TYPES IN CALCULATION OF PERCENTAGE.**—With respect to bids to furnish diabetic testing strip products on or after January 1, 2019, in determining under subparagraph (A) whether a bid submitted by an entity under such subparagraph covers 50 percent (or such higher percentage as the Secretary may specify) of all types of diabetic testing strip products, the Secretary may not attribute a percentage to types of diabetic testing strip products that the Secretary does not identify by brand, model, and market share volume.

“(E) **ADHERENCE TO DEMONSTRATION.**—

“(i) **IN GENERAL.**—In the case of an entity that is furnishing diabetic testing strip products on or after January 1, 2019, under a contract entered into under the competition conducted pursuant to paragraph (1), the Secretary shall establish a process to monitor, on an ongoing basis, the extent to which such entity continues to cover the product types included in the entity’s bid.

“(ii) **TERMINATION.**—If the Secretary determines that an entity described in clause (i) fails to maintain in inventory, or otherwise maintain ready access to (through requirements, contracts, or otherwise) a type of product included in the entity’s bid, the Secretary may terminate such contract unless the Secretary finds that the failure of the entity to maintain inventory of, or ready access to, the product is the result of the discontinuation of the product by the product manufacturer, a market-wide shortage of the product, or the introduction of a newer model or version of the product in the market involved.”.

(b) **CODIFYING AND EXPANDING ANTI-SWITCHING RULE.**—Section 1847(b) of the Social Security Act (42 U.S.C. 1395w–3(b)), as amended by subsection (a)(1), is further amended—

(1) by redesignating paragraph (11) as paragraph (12); and

(2) by inserting after paragraph (10) the following new paragraph:

“(11) **ADDITIONAL SPECIAL RULES IN CASE OF COMPETITION FOR DIABETIC TESTING STRIPS.**—

“(A) **IN GENERAL.**—With respect to an entity that is furnishing diabetic testing strip products to individuals under a contract entered into under the competitive acquisition program established under this section, the entity shall furnish to each individual a brand of such products that is compatible with the home blood glucose monitor selected by the individual.

“(B) **PROHIBITION ON INFLUENCING AND INCENTIVIZING.**—An entity described in subparagraph (A) may not attempt to influence or incentivize an individual to switch the brand of glucose monitor or diabetic testing strip product selected by the individual, including by—

“(i) persuading, pressuring, or advising the individual to switch; or

“(ii) furnishing information about alternative brands to the individual where the individual has not requested such information.

“(C) **PROVISION OF INFORMATION.**—

“(i) STANDARDIZED INFORMATION.—Not later than January 1, 2019, the Secretary shall develop and make available to entities described in subparagraph (A) standardized information that describes the rights of an individual with respect to such an entity. The information described in the preceding sentence shall include information regarding—

“(I) the requirements established under subparagraphs (A) and (B);

“(II) the right of the individual to purchase diabetic testing strip products from another mail order supplier of such products or a retail pharmacy if the entity is not able to furnish the brand of such product that is compatible with the home blood glucose monitor selected by the individual; and

“(III) the right of the individual to return diabetic testing strip products furnished to the individual by the entity.

“(ii) REQUIREMENT.—With respect to diabetic testing strip products furnished on or after the date on which the Secretary develops the standardized information under clause (i), an entity described in subparagraph (A) may not communicate directly to an individual until the entity has verbally provided the individual with such standardized information.

“(D) ORDER REFILLS.—With respect to diabetic testing strip products furnished on or after January 1, 2019, the Secretary shall require an entity furnishing diabetic testing strip products to an individual to contact and receive a request from the individual for such products not more than 14 days prior to dispensing a refill of such products to the individual.”

(c) IMPLEMENTATION; NON-APPLICATION OF THE PAPERWORK REDUCTION ACT.—

(1) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the provisions of, and amendments made by, this section by program instruction or otherwise.

(2) NON-APPLICATION OF THE PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code (commonly referred to as the “Paperwork Reduction Act of 1995”), shall not apply to this section or the amendments made by this section.

PURPOSE AND SUMMARY

H.R. 3271 was introduced on July 17, 2017, by Rep. Diana DeGette (D-CO). H.R. 3271 would address several issues beneficiaries have reported facing under the competitive bidding program regarding Diabetes Test Strips (DTS). Many of these issues stem from how the Centers for Medicare and Medicaid Services (CMS) has enforced certain beneficiary protections.

BACKGROUND AND NEED FOR LEGISLATION

In establishing the Medicare Competitive Bidding Program (CBP), Congress and CMS included rules intended to ensure that beneficiaries would continue to have access to the blood glucose test systems of their choice. Unfortunately, based on testimony presented to the Subcommittee, the first rounds of the CBP and subsequent reports by the Office of Inspector General (OIG) revealed significant shortcomings in these protections. H.R. 3271 strengthens protections for Medicare beneficiaries purchasing blood glucose testing equipment and supplies through Medicare’s National Mail Order Competitive Bidding Program. H.R. 3271 would address these shortcomings so that in future, CBP rounds beneficiaries have access to preferred and familiar test systems.

H.R. 3271 will strengthen the “50 Percent Rule” first established by Congress in 2008. By requiring suppliers’ bids to include at least 50 percent of the types of test systems on the market before the implementation of CBP, this rule seeks to ensure that beneficiaries are likely to have access to the testing systems they used before CBP. However, a recent study by the American Association of Dia-

betes Educators showed that under CBP, beneficiaries actually have access to far fewer types of testing systems. H.R. 3271 will require suppliers to demonstrate that they have an intent and ability to maintain an inventory of products consistent with their bid and require suppliers to adhere to the 50 percent rule throughout the life of their contract. Further, this bill bolsters the Anti-Switching Rule, a beneficiary protection established by CMS through a regulation that prohibits suppliers from encouraging beneficiaries to switch from one testing system to another. H.R. 3271 would codify and enhance the Anti-Switching Rule by ensuring beneficiaries know their rights to receive compatible test strips with their blood glucose monitors.

COMMITTEE ACTION

On July 20, 2017, the Subcommittee on Health held a hearing on H.R. 3271. The hearing was entitled “Examining Bipartisan Legislation to Improve the Medicare Program.” The Subcommittee received testimony from:

- Christel Aprigliano, CEO, Diabetes Patient Advocacy Coalition;
- Lisa Bardach, Speech-Language Pathologist, ALS of Michigan;
- K. Eric De Jonge, President-Elect, American Academy of Home Care Medicine (AAHCM);
- Cletis Earle, Chairman-Elect, CHIME Board of Trustees;
- Mary Grealy, President, Healthcare Leadership Council;
- Deepak A. Kapoor, Chairman and CEO, Integrated Medical Professionals;
- Brett Kissela, Chair, Department of Neurology and Rehabilitation Medicine, University of Cincinnati Gardner Neuroscience Institute, on behalf of American Academy of Neurology;
- Justin Moore, CEO, American Physical Therapy Association;
- Alan E. Morrison, Chair, Diagnostic Services Committee, National Association for the Support of Long Term Care (NASL);
- Varner Richards, Board Chair, National Home Infusion Association; and
- Stacy Sanders, Federal Policy Director, Medicare Rights Center.

On September 13, 2017, the Subcommittee on Health met in open markup session and forwarded H.R. 3271, as amended, to the full Committee by a voice vote. On October 4, 2017, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 1148, as amended, favorably reported to the House by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 3271 reported.

OVERSIGHT FINDINGS AND RECOMMENDATIONS

Pursuant to clause 2(b)(1) of rule X and clause 3(c)(1) of rule XIII, the Committee held a hearing and made findings that are reflected in this report.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to clause 3(c)(2) of rule XIII, the Committee finds that H.R. 3271 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, October 24, 2017.

Hon. GREG WALDEN,
*Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 3271, the Protecting Access to Diabetes Supplies Act of 2017.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Lara Robillard.

Sincerely,

KEITH HALL,
Director.

Enclosure.

H.R. 3271—Protecting Access to Diabetes Supplies Act of 2017

Summary: H.R. 3271 would codify certain requirements with respect to Medicare coverage of diabetic testing supplies (DTS). Based on current Medicare program and payment rules for DTS, CBO estimates that enacting H.R. 3271 would have no effect on the federal budget.

Enacting H.R. 3271 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply. CBO estimates that enacting H.R. 3271 would not increase net direct spending or on-budget deficits in one or more of the four consecutive 10-year periods beginning in 2028.

H.R. 3271 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA).

Basis of estimate: Durable medical equipment (DME), which includes items like wheelchairs, hospital beds, and oxygen supplies, is a benefit within the Medicare program. The DME benefit includes supplies necessary to monitor blood sugar levels for people with diabetes, including glucose monitors and strips used to test blood samples collectively called diabetic testing supplies (DTS). For some DME items, Medicare payment is based on a system in which suppliers compete to furnish DME, including DTS, to Medi-

care beneficiaries, with prices based on supplier bids. For DTS, Medicare payments are set for the nation as a whole and are pegged to prices for items delivered by mail-order suppliers. Beneficiaries can choose to receive DTS by mail or go to a local pharmacy. Suppliers who furnish DTS to Medicare beneficiaries must meet certain standards, including coverage of commonly-available brands of test strips, and may not switch beneficiaries from one brand to another without their permission.

In CBO's judgment, H.R. 3271 would codify current practice with respect to diabetic testing strips, including the requirement that suppliers demonstrate the ability to furnish the strips on which their bids are based. The bill would also require the Centers for Medicare and Medicaid Services (CMS) to monitor suppliers to ensure that they continue to offer the brand of strips included in their bids.

CBO estimates that enacting H.R. 3271 would not affect the federal budget, but there is some uncertainty in that estimate. The legislation that established Medicare's DME competitive bidding program left considerable discretion to CMS to administer the program and to set its parameters through notice-and-comment rule-making and other guidance. If CMS continues to manage the competitive bidding program as it has, then CBO estimates that H.R. 3271 would codify current practice with respect to DTS and would have no budgetary impact. It is possible, however, that CMS could change how the DME competitive bidding system works in such a way that the requirements of H.R. 3271 would have a budgetary impact. For example, if CMS announced that Medicare would cover only one brand of testing strip and do so at a price below the current payment amount, then H.R. 3271, which codifies requirements for offering multiple brands, would probably increase direct spending in the Medicare program.

Another source of uncertainty with respect to H.R. 3271 is timing. Medicare uses supplier bids to set payment amounts for a set period of time, generally three years (for example, December 1, 2016 through December 31, 2018). In the past, it has taken CMS about 18 months to prepare for each round. A new round of competitively bid prices is set to take effect on January 1, 2019, so CBO expected that CMS would have announced any policy changes earlier this year. As yet, CMS has not made any public pronouncement about the January 2019 round and has not established any requirements for suppliers who wish to bid. H.R. 3271 would apply to "bids to furnish such types of products on or after January 1, 2019." As a result, CBO anticipates that its provisions would apply to the next round of competitive bidding, whenever it begins. Although the uncertainty around timing does not affect CBO's estimate of H.R. 3271, it does underscore the overall uncertainty of CBO's estimate, as it does not have updated information to inform its analysis.

Increase in long-term direct spending and deficits: CBO estimates that enacting the legislation would not increase net direct spending or on-budget deficits in one or more of the four consecutive 10-year periods beginning in 2028.

Estimated impact on state, local, and tribal governments: H.R. 3271 contains no intergovernmental or private-sector mandates as defined in UMRA.

Estimate prepared by: Federal costs: Lara Robillard; Impact on state, local, and tribal governments and the private sector: Amy Petz.

Estimate approved by: Theresa Gullo, Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to address several issues beneficiaries have reported facing under the competitive bidding program regarding DTS.

DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 3271 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111-139 or the most recent Catalog of Federal Domestic Assistance.

COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

earmark, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 3271 contains no earmarks, limited tax benefits, or limited tariff benefits.

DISCLOSURE OF DIRECTED RULE MAKINGS

Pursuant to section 3(i) of H. Res. 5, the Committee finds that H.R. 3271 contains no directed rule makings.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 provides that the Act may be cited as the “Protecting Access to Diabetes Supplies Act of 2017.”

Section 2. Strengthening rules in case of competition for diabetic testing strips

Section 2 would specify the types of data the Department of Health and Human Services (HHS) must collect from entities entering the competitive acquisition program for diabetic testing strips when verifying that an entity’s bid satisfies the requirement of covering at least 50 percent of all types of diabetic testing strip products and would create additional requirements on the Centers for Medicare and Medicaid Services to provide oversight and enforcement of the requirement.

The section also would require entities furnishing diabetic testing strip products under the competitive acquisition program to furnish strips compatible with a given beneficiary’s home blood glucose monitor, and prohibits entities from incentivizing a beneficiary to switch to a different brand. HHS would be required to make available information describing the rights of beneficiaries in the program. Entities would not be allowed to solicit orders from individuals enrolled in the program more than 14 days prior to dispensing said order.

Finally, the section specifies how HHS may implement the provisions of the bill and specifies that the Paperwork Reduction Act of 1995 shall not apply to the amendments made by the bill.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

SOCIAL SECURITY ACT

* * * * *

TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

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PART B—SUPPLEMENTARY MEDICAL INSURANCE BENEFITS FOR THE AGED AND DISABLED

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COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES

SEC. 1847. (a) ESTABLISHMENT OF COMPETITIVE ACQUISITION PROGRAMS.—

(1) IMPLEMENTATION OF PROGRAMS.—

(A) IN GENERAL.—The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part of competitively priced items and services (described in paragraph (2)) for which payment is made under this part. Such areas may differ for different items and services.

(B) PHASED-IN IMPLEMENTATION.—The programs—

(i) shall be phased in among competitive acquisition areas in a manner consistent with subparagraph (D) so that the competition under the programs occurs in—

(I) 10 of the largest metropolitan statistical areas in 2007;

(II) an additional 91 of the largest metropolitan statistical areas in 2011; and

(III) additional areas after 2011 (or, in the case of national mail order for items and services, after 2010); and

(ii) may be phased in first among the highest cost and highest volume items and services or those items and services that the Secretary determines have the largest savings potential.

(C) WAIVER OF CERTAIN PROVISIONS.—In carrying out the programs, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

(D) CHANGES IN COMPETITIVE ACQUISITION PROGRAMS.—

(i) ROUND 1 OF COMPETITIVE ACQUISITION PROGRAM.—Notwithstanding subparagraph (B)(i)(I) and in implementing the first round of the competitive acquisition programs under this section—

(I) the contracts awarded under this section before the date of the enactment of this subparagraph are terminated, no payment shall be made under this title on or after the date of the enactment of this subparagraph based on such a contract, and, to the extent that any damages may be applicable as a result of the termination of such contracts, such damages shall be payable from the Federal Supplementary Medical Insurance Trust Fund under section 1841;

(II) the Secretary shall conduct the competition for such round in a manner so that it occurs in 2009 with respect to the same items and services and the same areas, except as provided in subclauses (III) and (IV);

(III) the Secretary shall exclude Puerto Rico so that such round of competition covers 9, instead of 10, of the largest metropolitan statistical areas; and

(IV) there shall be excluded negative pressure wound therapy items and services.

Nothing in subclause (I) shall be construed to provide an independent cause of action or right to administrative or

judicial review with regard to the termination provided under such subclause.

(ii) **ROUND 2 OF COMPETITIVE ACQUISITION PROGRAM.**—In implementing the second round of the competitive acquisition programs under this section described in subparagraph (B)(i)(II)—

(I) the metropolitan statistical areas to be included shall be those metropolitan statistical areas selected by the Secretary for such round as of June 1, 2008;

(II) the Secretary shall include the next 21 largest metropolitan statistical areas by total population (after those selected under subclause (I)) for such round; and

(III) the Secretary may subdivide metropolitan statistical areas with populations (based upon the most recent data from the Census Bureau) of at least 8,000,000 into separate areas for competitive acquisition purposes.

(iii) **EXCLUSION OF CERTAIN AREAS IN SUBSEQUENT ROUNDS OF COMPETITIVE ACQUISITION PROGRAMS.**—In implementing subsequent rounds of the competitive acquisition programs under this section, including under subparagraph (B)(i)(III), for competitions occurring before 2015, the Secretary shall exempt from the competitive acquisition program (other than national mail order) the following:

(I) Rural areas.

(II) Metropolitan statistical areas not selected under round 1 or round 2 with a population of less than 250,000.

(III) Areas with a low population density within a metropolitan statistical area that is otherwise selected, as determined for purposes of paragraph (3)(A).

(E) **VERIFICATION BY OIG.**—The Inspector General of the Department of Health and Human Services shall, through post-award audit, survey, or otherwise, assess the process used by the Centers for Medicare & Medicaid Services to conduct competitive bidding and subsequent pricing determinations under this section that are the basis for pivotal bid amounts and single payment amounts for items and services in competitive bidding areas under rounds 1 and 2 of the competitive acquisition programs under this section and may continue to verify such calculations for subsequent rounds of such programs.

(F) **SUPPLIER FEEDBACK ON MISSING FINANCIAL DOCUMENTATION.**—

(i) **IN GENERAL.**—In the case of a bid where one or more covered documents in connection with such bid have been submitted not later than the covered document review date specified in clause (ii), the Secretary—

(I) shall provide, by not later than 45 days (in the case of the first round of the competitive acquisition programs as described in subparagraph (B)(i)(I)) or 90 days (in the case of a subsequent round of such programs) after the covered document review date, for notice to the bidder of

all such documents that are missing as of the covered document review date; and

(II) may not reject the bid on the basis that any covered document is missing or has not been submitted on a timely basis, if all such missing documents identified in the notice provided to the bidder under subclause (I) are submitted to the Secretary not later than 10 business days after the date of such notice.

(ii) COVERED DOCUMENT REVIEW DATE.—The covered document review date specified in this clause with respect to a competitive acquisition program is the later of—

(I) the date that is 30 days before the final date specified by the Secretary for submission of bids under such program; or

(II) the date that is 30 days after the first date specified by the Secretary for submission of bids under such program.

(iii) LIMITATIONS OF PROCESS.—The process provided under this subparagraph—

(I) applies only to the timely submission of covered documents;

(II) does not apply to any determination as to the accuracy or completeness of covered documents submitted or whether such documents meet applicable requirements;

(III) shall not prevent the Secretary from rejecting a bid based on any basis not described in clause (i)(II); and

(IV) shall not be construed as permitting a bidder to change bidding amounts or to make other changes in a bid submission.

(iv) COVERED DOCUMENT DEFINED.—In this subparagraph, the term “covered document” means a financial, tax, or other document required to be submitted by a bidder as part of an original bid submission under a competitive acquisition program in order to meet required financial standards. Such term does not include other documents, such as the bid itself or accreditation documentation.

(G) REQUIRING BID BONDS FOR BIDDING ENTITIES.—With respect to rounds of competitions beginning under this subsection for contracts beginning not earlier than January 1, 2017, and not later than January 1, 2019, an entity may not submit a bid for a competitive acquisition area unless, as of the deadline for bid submission, the entity has obtained (and provided the Secretary with proof of having obtained) a bid surety bond (in this paragraph referred to as a “bid bond”) in a form specified by the Secretary consistent with subparagraph (H) and in an amount that is not less than \$50,000 and not more than \$100,000 for each competitive acquisition area in which the entity submits the bid.

(H) TREATMENT OF BID BONDS SUBMITTED.—

(i) FOR BIDDERS THAT SUBMIT BIDS AT OR BELOW THE MEDIAN AND ARE OFFERED BUT DO NOT ACCEPT THE CONTRACT.—In the case of a bidding entity that is offered a contract for any product category for a competitive acquisition area, if—

(I) the entity's composite bid for such product category and area was at or below the median composite bid rate for all bidding entities included in the calculation of the single payment amounts for such product category and area; and

(II) the entity does not accept the contract offered for such product category and area, the bid bond submitted by such entity for such area shall be forfeited by the entity and the Secretary shall collect on it.

(ii) TREATMENT OF OTHER BIDDERS.—In the case of a bidding entity for any product category for a competitive acquisition area, if the entity does not meet the bid forfeiture conditions in subclauses (I) and (II) of clause (i) for any product category for such area, the bid bond submitted by such entity for such area shall be returned within 90 days of the public announcement of the contract suppliers for such area.

(2) ITEMS AND SERVICES DESCRIBED.—The items and services referred to in paragraph (1) are the following:

(A) DURABLE MEDICAL EQUIPMENT AND MEDICAL SUPPLIES.—Covered items (as defined in section 1834(a)(13)) for which payment would otherwise be made under section 1834(a), including items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with durable medical equipment, but excluding class III devices under the Federal Food, Drug, and Cosmetic Act, excluding certain complex rehabilitative power wheelchairs recognized by the Secretary as classified within group 3 or higher (and related accessories when furnished in connection with such wheelchairs), and excluding drugs and biologicals described in section 1842(o)(1)(D).

(B) OTHER EQUIPMENT AND SUPPLIES.—Items and services described in section 1842(s)(2)(D), other than parenteral nutrients, equipment, and supplies.

(C) OFF-THE-SHELF ORTHOTICS.—Orthotics described in section 1861(s)(9) for which payment would otherwise be made under section 1834(h) which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual.

(3) EXCEPTION AUTHORITY.—In carrying out the programs under this section, the Secretary may exempt—

(A) rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item or service; and

(B) items and services for which the application of competitive acquisition is not likely to result in significant savings.

(4) SPECIAL RULE FOR CERTAIN RENTED ITEMS OF DURABLE MEDICAL EQUIPMENT AND OXYGEN.—In the case of a covered item for which payment is made on a rental basis under section 1834(a) and in the case of payment for oxygen under section 1834(a)(5), the Secretary shall establish a process by

which rental agreements for the covered items and supply arrangements with oxygen suppliers entered into before the application of the competitive acquisition program under this section for the item may be continued notwithstanding this section. In the case of any such continuation, the supplier involved shall provide for appropriate servicing and replacement, as required under section 1834(a).

(5) PHYSICIAN AUTHORIZATION.—

(A) IN GENERAL.—With respect to items or services included within a particular HCPCS code, the Secretary may establish a process for certain items and services under which a physician may prescribe a particular brand or mode of delivery of an item or service within such code if the physician determines that use of the particular item or service would avoid an adverse medical outcome on the individual, as determined by the Secretary.

(B) NO EFFECT ON PAYMENT AMOUNT.—A prescription under subparagraph (A) shall not affect the amount of payment otherwise applicable for the item or service under the code involved.

(6) APPLICATION.—For each competitive acquisition area in which the program is implemented under this subsection with respect to items and services, the payment basis determined under the competition conducted under subsection (b) shall be substituted for the payment basis otherwise applied under section 1834(a), section 1834(h), or section 1842(s), as appropriate.

(7) EXEMPTION FROM COMPETITIVE ACQUISITION.—The programs under this section shall not apply to the following:

(A) CERTAIN OFF-THE-SHELF ORTHOTICS.—Items and services described in paragraph (2)(C) if furnished—

(i) by a physician or other practitioner (as defined by the Secretary) to the physician's or practitioner's own patients as part of the physician's or practitioner's professional service; or

(ii) by a hospital to the hospital's own patients during an admission or on the date of discharge.

(B) CERTAIN DURABLE MEDICAL EQUIPMENT.—Those items and services described in paragraph (2)(A)—

(i) that are furnished by a hospital to the hospital's own patients during an admission or on the date of discharge; and

(ii) to which such programs would not apply, as specified by the Secretary, if furnished by a physician to the physician's own patients as part of the physician's professional service.

(b) PROGRAM REQUIREMENTS.—

(1) IN GENERAL.—The Secretary shall conduct a competition among entities supplying items and services described in subsection (a)(2) for each competitive acquisition area in which the program is implemented under subsection (a) with respect to such items and services.

(2) CONDITIONS FOR AWARDED CONTRACT.—

(A) IN GENERAL.—The Secretary may not award a contract to any entity under the competition conducted in a competitive acquisition area pursuant to paragraph (1) to

furnish such items or services unless the Secretary finds all of the following:

(i) The entity meets applicable quality standards specified by the Secretary under section 1834(a)(20).

(ii) The entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers.

(iii) The total amounts to be paid to contractors in a competitive acquisition area are expected to be less than the total amounts that would otherwise be paid.

(iv) Access of individuals to a choice of multiple suppliers in the area is maintained.

(v) The entity meets applicable State licensure requirements.

(B) TIMELY IMPLEMENTATION OF PROGRAM.—Any delay in the implementation of quality standards under section 1834(a)(20) or delay in the receipt of advice from the program oversight committee established under subsection (c) shall not delay the implementation of the competitive acquisition program under this section.

(3) CONTENTS OF CONTRACT.—

(A) IN GENERAL.—A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify.

(B) TERM OF CONTRACTS.—The Secretary shall recompete contracts under this section not less often than once every 3 years.

(C) DISCLOSURE OF SUBCONTRACTORS.—

(i) INITIAL DISCLOSURE.—Not later than 10 days after the date a supplier enters into a contract with the Secretary under this section, such supplier shall disclose to the Secretary, in a form and manner specified by the Secretary, the information on—

(I) each subcontracting relationship that such supplier has in furnishing items and services under the contract; and

(II) whether each such subcontractor meets the requirement of section 1834(a)(20)(F)(i), if applicable to such subcontractor.

(ii) SUBSEQUENT DISCLOSURE.—Not later than 10 days after such a supplier subsequently enters into a subcontracting relationship described in clause (i)(II), such supplier shall disclose to the Secretary, in such form and manner, the information described in subclauses (I) and (II) of clause (i).

(4) LIMIT ON NUMBER OF CONTRACTORS.—

(A) IN GENERAL.—The Secretary may limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for items and services covered under the contracts. In awarding contracts, the Secretary shall take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of individuals for such items

or services in the geographic area covered under the contract on a timely basis.

(B) MULTIPLE WINNERS.—The Secretary shall award contracts to multiple entities submitting bids in each area for an item or service.

(5) PAYMENT.—

(A) IN GENERAL.—Payment under this part for competitively priced items and services described in subsection (a)(2) shall be based on bids submitted and accepted under this section for such items and services. Based on such bids the Secretary shall determine a single payment amount for each item or service in each competitive acquisition area.

(B) REDUCED BENEFICIARY COST-SHARING.—

(i) APPLICATION OF COINSURANCE.—Payment under this section for items and services shall be in an amount equal to 80 percent of the payment basis described in subparagraph (A).

(ii) APPLICATION OF DEDUCTIBLE.—Before applying clause (i), the individual shall be required to meet the deductible described in section 1833(b).

(C) PAYMENT ON ASSIGNMENT-RELATED BASIS.—Payment for any item or service furnished by the entity may only be made under this section on an assignment-related basis.

(D) CONSTRUCTION.—Nothing in this section shall be construed as precluding the use of an advanced beneficiary notice with respect to a competitively priced item and service.

(6) PARTICIPATING CONTRACTORS.—

(A) IN GENERAL.—Except as provided in subsection (a)(4), payment shall not be made for items and services described in subsection (a)(2) furnished by a contractor and for which competition is conducted under this section unless—

(i) the contractor has submitted a bid for such items and services under this section; and

(ii) the Secretary has awarded a contract to the contractor for such items and services under this section.

(B) BID DEFINED.—In this section, the term “bid” means an offer to furnish an item or service for a particular price and time period that includes, where appropriate, any services that are attendant to the furnishing of the item or service.

(C) RULES FOR MERGERS AND ACQUISITIONS.—In applying subparagraph (A) to a contractor, the contractor shall include a successor entity in the case of a merger or acquisition, if the successor entity assumes such contract along with any liabilities that may have occurred thereunder.

(D) PROTECTION OF SMALL SUPPLIERS.—In developing procedures relating to bids and the awarding of contracts under this section, the Secretary shall take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program under this section.

(7) CONSIDERATION IN DETERMINING CATEGORIES FOR BIDS.—The Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

(8) AUTHORITY TO CONTRACT FOR EDUCATION, MONITORING, OUTREACH, AND COMPLAINT SERVICES.—The Secretary may enter into contracts with appropriate entities to address complaints from individuals who receive items and services from an entity with a contract under this section and to conduct appropriate education of and outreach to such individuals and monitoring quality of services with respect to the program.

(9) AUTHORITY TO CONTRACT FOR IMPLEMENTATION.—The Secretary may contract with appropriate entities to implement the competitive bidding program under this section.

(10) SPECIAL RULE IN CASE OF COMPETITION FOR DIABETIC TESTING STRIPS.—

(A) IN GENERAL.—With respect to the competitive acquisition program for diabetic testing strips conducted after the first round of the competitive acquisition programs, if an entity does not demonstrate to the Secretary that its bid covers types of diabetic testing strip products that, in the aggregate and taking into account volume for the different products, cover 50 percent (or such higher percentage as the Secretary may specify) of all such types of products, the Secretary shall reject such bid. [The volume for such types of products may be determined in accordance with such data (which may be market based data) as the Secretary recognizes.] *With respect to bids to furnish such types of products on or after January 1, 2019, the volume for such types of products shall be determined by the Secretary through the use of multiple sources of data (from mail order and non-mail order Medicare markets), including market-based data measuring sales of diabetic testing strip products that are not exclusively sold by a single retailer from such markets.*

(B) STUDY OF TYPES OF TESTING STRIP PRODUCTS.—Before 2011, the Inspector General of the Department of Health and Human Services shall conduct a study to determine the types of diabetic testing strip products by volume that could be used to make determinations pursuant to subparagraph (A) for the first competition under the competitive acquisition program described in such subparagraph and submit to the Secretary a report on the results of the study. The Inspector General shall also conduct such a study and submit such a report before the Secretary conducts a subsequent competitive acquisition program described in subparagraph (A).

(C) DEMONSTRATION OF ABILITY TO FURNISH TYPES OF DIABETIC TESTING STRIP PRODUCTS.—*With respect to bids to furnish diabetic testing strip products on or after January 1, 2019, under the program described in subparagraph (A), the Secretary shall reject a bid submitted by an entity if the entity does not attest to the Secretary and demonstrate, through letters of intent with manufacturers, wholesalers, or other suppliers, or other evidence as the Secretary may*

specify, that the entity has the ability to obtain an inventory of the types and quantities of diabetic testing strip products that will allow the entity to furnish such products in a manner consistent with its bid.

(D) *USE OF UNLISTED TYPES IN CALCULATION OF PERCENTAGE.*—With respect to bids to furnish diabetic testing strip products on or after January 1, 2019, in determining under subparagraph (A) whether a bid submitted by an entity under such subparagraph covers 50 percent (or such higher percentage as the Secretary may specify) of all types of diabetic testing strip products, the Secretary may not attribute a percentage to types of diabetic testing strip products that the Secretary does not identify by brand, model, and market share volume.

(E) *ADHERENCE TO DEMONSTRATION.*—

(i) *IN GENERAL.*—In the case of an entity that is furnishing diabetic testing strip products on or after January 1, 2019, under a contract entered into under the competition conducted pursuant to paragraph (1), the Secretary shall establish a process to monitor, on an ongoing basis, the extent to which such entity continues to cover the product types included in the entity's bid.

(ii) *TERMINATION.*—If the Secretary determines that an entity described in clause (i) fails to maintain in inventory, or otherwise maintain ready access to (through requirements, contracts, or otherwise) a type of product included in the entity's bid, the Secretary may terminate such contract unless the Secretary finds that the failure of the entity to maintain inventory of, or ready access to, the product is the result of the discontinuation of the product by the product manufacturer, a market-wide shortage of the product, or the introduction of a newer model or version of the product in the market involved.

(11) *ADDITIONAL SPECIAL RULES IN CASE OF COMPETITION FOR DIABETIC TESTING STRIPS.*—

(A) *IN GENERAL.*—With respect to an entity that is furnishing diabetic testing strip products to individuals under a contract entered into under the competitive acquisition program established under this section, the entity shall furnish to each individual a brand of such products that is compatible with the home blood glucose monitor selected by the individual.

(B) *PROHIBITION ON INFLUENCING AND INCENTIVIZING.*—An entity described in subparagraph (A) may not attempt to influence or incentivize an individual to switch the brand of glucose monitor or diabetic testing strip product selected by the individual, including by—

(i) persuading, pressuring, or advising the individual to switch; or

(ii) furnishing information about alternative brands to the individual where the individual has not requested such information.

(C) *PROVISION OF INFORMATION.*—

(i) *STANDARDIZED INFORMATION.*—Not later than January 1, 2019, the Secretary shall develop and make available to entities described in subparagraph (A) standardized information that describes the rights of an individual with respect to such an entity. The information described in the preceding sentence shall include information regarding—

(I) the requirements established under subparagraphs (A) and (B);

(II) the right of the individual to purchase diabetic testing strip products from another mail order supplier of such products or a retail pharmacy if the entity is not able to furnish the brand of such product that is compatible with the home blood glucose monitor selected by the individual; and

(III) the right of the individual to return diabetic testing strip products furnished to the individual by the entity.

(ii) *REQUIREMENT.*—With respect to diabetic testing strip products furnished on or after the date on which the Secretary develops the standardized information under clause (i), an entity described in subparagraph (A) may not communicate directly to an individual until the entity has verbally provided the individual with such standardized information.

(D) *ORDER REFILLS.*—With respect to diabetic testing strip products furnished on or after January 1, 2019, the Secretary shall require an entity furnishing diabetic testing strip products to an individual to contact and receive a request from the individual for such products not more than 14 days prior to dispensing a refill of such products to the individual.

[(11)] (12) *NO ADMINISTRATIVE OR JUDICIAL REVIEW.*—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of—

(A) the establishment of payment amounts under paragraph (5);

(B) the awarding of contracts under this section;

(C) the designation of competitive acquisition areas under subsection (a)(1)(A) and the identification of areas under subsection (a)(1)(D)(iii);

(D) the phased-in implementation under subsection (a)(1)(B) and implementation of subsection (a)(1)(D);

(E) the selection of items and services for competitive acquisition under subsection (a)(2);

(F) the bidding structure and number of contractors selected under this section; or

(G) the implementation of the special rule described in paragraph (10).

(c) *PROGRAM ADVISORY AND OVERSIGHT COMMITTEE.*—

(1) *ESTABLISHMENT.*—The Secretary shall establish a Program Advisory and Oversight Committee (hereinafter in this section referred to as the “Committee”).

(2) MEMBERSHIP; TERMS.—The Committee shall consist of such members as the Secretary may appoint who shall serve for such term as the Secretary may specify.

(3) DUTIES.—

(A) ADVICE.—The Committee shall provide advice to the Secretary with respect to the following functions:

(i) The implementation of the program under this section.

(ii) The establishment of financial standards for purposes of subsection (b)(2)(A)(ii).

(iii) The establishment of requirements for collection of data for the efficient management of the program.

(iv) The development of proposals for efficient interaction among manufacturers, providers of services, suppliers (as defined in section 1861(d)), and individuals.

(v) The establishment of quality standards under section 1834(a)(20).

(B) ADDITIONAL DUTIES.—The Committee shall perform such additional functions to assist the Secretary in carrying out this section as the Secretary may specify.

(4) INAPPLICABILITY OF FACa.—The provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply.

(5) TERMINATION.—The Committee shall terminate on December 31, 2011.

(d) REPORT.—Not later than July 1, 2011, the Secretary shall submit to Congress a report on the programs under this section. The report shall include information on savings, reductions in cost-sharing, access to and quality of items and services, and satisfaction of individuals.

(f) COMPETITIVE ACQUISITION OMBUDSMAN.—The Secretary shall provide for a competitive acquisition ombudsman within the Centers for Medicare & Medicaid Services in order to respond to complaints and inquiries made by suppliers and individuals relating to the application of the competitive acquisition program under this section. The ombudsman may be within the office of the Medicare Beneficiary Ombudsman appointed under section 1808(c). The ombudsman shall submit to Congress an annual report on the activities under this subsection, which report shall be coordinated with the report provided under section 1808(c)(2)(C).

* * * * *

EXCHANGE OF LETTERS WITH ADDITIONAL COMMITTEES OF REFERRAL

Congress of the United States U.S. House of Representatives

COMMITTEE ON WAYS AND MEANS

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DAVID STEWART, STAFF DIRECTOR

December 5, 2017

The Honorable Greg Walden Chairman Committee on Energy and Commerce 2125 Rayburn House Office Building Washington, DC 20515

Dear Chairman Walden,

I am writing with respect to H.R. 3271, the "Protecting Access to Diabetes Supplies Act of 2017," on which the Committee on Ways and Means was granted an additional referral.

As a result of your having consulted with us on provisions in H.R. 3271 that fall within the Rule X jurisdiction of the Committee on Ways and Means, I agree to waive formal consideration of this bill so that it may move expeditiously to the floor. The Committee on Ways and Means takes this action with the mutual understanding that we do not waive any jurisdiction over the subject matter contained in this or similar legislation, and the Committee will be appropriately consulted and involved as the bill or similar legislation moves forward so that we may address any remaining issues that fall within our jurisdiction. The Committee also reserves the right to seek appointment of an appropriate number of conferees to any House-Senate conference involving this or similar legislation, and requests your support for such request.

Finally, I would appreciate your response to this letter confirming this understanding, and would ask that a copy of our exchange of letters on this matter be included in the Congressional Record during floor consideration of H.R. 3271.

Sincerely,

[Handwritten signature of Kevin Brady]

Kevin Brady Chairman

- cc: The Honorable Paul Ryan, Speaker The Honorable Richard E. Neal The Honorable Frank Pallone Thomas J. Wickham, Jr., Parliamentarian

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS
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December 5, 2017

The Honorable Kevin Brady
Chairman
Committee on Ways and Means
1102 Longworth House Office Building
Washington, DC 20515

Dear Chairman Brady:

Thank you for your letter regarding H.R. 3271, Protecting Access to Diabetes Supplies Act of 2017, on which the Committee on Ways and Means was granted an additional referral.

I appreciate your agreeing to waive formal consideration of H.R. 3271 in order to allow the bill to move expeditiously to the House floor.

I agree that by foregoing consideration on H.R. 3271 at this time, the Committee on Ways and Means does not waive any jurisdiction over subject matter contained in this or similar legislation, and that the Committee will be appropriately consulted and involved as this bill or similar legislation moves forward. I also agree that the Committee reserves the right to seek appointment of an appropriate number of conferees to any House-Senate conference involving this or similar legislation, and I will support any such request.

Finally, I will include a copy of your letter and this response in the Congressional Record during the floor consideration of this bill.

Sincerely,


Greg Walden
Chairman

