

MEDICARE DRUG PRICE NEGOTIATION PROGRAM AGREEMENT
(hereinafter referred to as the “Agreement”)

Between

the Centers for Medicare & Medicaid Services (CMS), pursuant to delegated authority of the Secretary of Health and Human Services

And

[Full Name of Manufacturer]
(hereinafter referred to as the “Manufacturer”)

For

[Name of Selected Drug]
(hereinafter referred to as the “Selected Drug”)

WHEREAS, pursuant to sections 1191 through 1198 of the Social Security Act (“the Act”), as set forth in the Inflation Reduction Act (IRA), Pub. L. 117-169, CMS is responsible for the administration of the Medicare Drug Price Negotiation Program (hereinafter referred to as the “Negotiation Program”), which sets forth a framework under which manufacturers and CMS may negotiate to determine a price (referred to as “maximum fair price” in the Act) for selected drugs in order for manufacturers to provide access to such price to maximum fair price eligible individuals; and

WHEREAS, CMS has designated the Manufacturer as the Primary Manufacturer, as defined in applicable guidance or regulations adopted in accordance with section 1193 of the Act, of the Selected Drug, and CMS has included the Selected Drug on the list of selected drugs published on [Date]; and

WHEREAS, the Manufacturer, if it reaches agreement with CMS, intends to provide access to the determined price pursuant to section 1193 of the Act and in accordance with how the price is computed and applied across different strengths and dosage forms of the Selected Drug as identified by CMS and updated, as applicable, in accordance with sections 1194(f), 1195(b), and 1196(a)(2) of the Act and applicable guidance and regulations, including where the Selected Drug is sold or marketed by any Secondary Manufacturers as defined in applicable guidance or regulations;

NOW THEREFORE, CMS, on behalf of the Department of Health and Human Services, and the Manufacturer, on its own behalf, in accordance with sections 1191 through 1198 of the Act, and all applicable guidance and regulations, hereby agree to the following:

I. Definitions

All terms included in this Agreement shall have the meaning given to them under the provisions of sections 1191 through 1198 of the Act and any applicable guidance and regulations implementing those provisions, except where such terms are expressly defined in this Agreement.

II. CMS and Manufacturer Responsibilities

CMS shall administer the Negotiation Program and the Manufacturer agrees to comply with all applicable requirements and conditions for the Negotiation Program set forth in sections 1191 through 1198 of the

Act and all applicable guidance and regulations implementing those provisions and any changes to the Act that affect the Negotiation Program.

Without limiting the foregoing, CMS and the Manufacturer agree:

- a) During the negotiation period for the initial price applicability year for the Selected Drug, in accordance with section 1194 of the Act and applicable guidance and regulations CMS and the Manufacturer shall negotiate to determine (and, by not later than the last date of such period, agree to) a maximum fair price for the Selected Drug of the Manufacturer in order for the Manufacturer to provide access to such price—
 - i. to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (A) of section 1191(c)(2) of the Act and are dispensed the Selected Drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed the Selected Drug) during, subject to paragraph (b) of this section, the price applicability period; and
 - ii. to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (B) of section 1191(c)(2) of the Act and are furnished or administered the Selected Drug during, subject to paragraph (b) of this section, the price applicability period.
- b) As applicable, CMS and the Manufacturer shall, in accordance with section 1194 of the Act and applicable guidance and regulations, renegotiate (and, by not later than the last date of the period of renegotiation, agree to) the maximum fair price for the Selected Drug, in order for the Manufacturer to provide access to such maximum fair price (as so renegotiated)—
 - i. to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (A) of section 1191(c)(2) of the Act and are dispensed the Selected Drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed the Selected Drug) during any year during the price applicability period (beginning after such renegotiation) with respect to such Selected Drug; and
 - ii. to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (B) of section 1191(c)(2) of the Act and are furnished or administered the Selected Drug during any year during the price applicability period (beginning after such renegotiation) with respect to such Selected Drug.
- c) Subject to paragraph (f) of this section and in accordance with applicable guidance and regulations, access to the maximum fair price (including as renegotiated pursuant to paragraph (b) of this section), with respect to such a Selected Drug, shall be provided by the Manufacturer to—
 - i. maximum fair price eligible individuals, who with respect to the Selected Drug are described in subparagraph (A) of section 1191(c)(2) of the Act, at the pharmacy, mail order service, or other dispenser at the point-of-sale of the Selected Drug (and shall be provided by the Manufacturer to the pharmacy, mail order service, or other dispenser, with respect to such maximum fair price eligible individuals who are dispensed the Selected Drug), as described in paragraph (a)(i) or (b)(i) of this section, as applicable; and
 - ii. hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to the Selected Drug are described in subparagraph (B) of section 1191(c)(2) of the Act and are furnished or administered the Selected Drug, as described in paragraph (a)(ii) or (b)(ii) of this section, as applicable.
- d) The Manufacturer shall submit to CMS, in a form and manner specified by CMS and in accordance with applicable guidance and regulations, for the negotiation period for the price

applicability period (and, if applicable, before any period of renegotiation pursuant to section 1194(f) of the Act), and for section 1192(f) of the Act, with respect to the Selected Drug—

- i. information on the non-Federal average manufacturer price (as defined in section 8126(h)(5) of title 38, United States Code) for the Selected Drug for the applicable year or period;
 - ii. information that CMS requires to carry out the negotiation (or renegotiation) process under sections 1191 through 1198 of the Act; and
 - iii. information that CMS requires to carry out section 1192(f) of the Act, including rebates under section 1192(f)(4) of the Act.
- e) The Manufacturer shall comply with requirements determined by CMS to be necessary for purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program, including in accordance with applicable guidance and regulations.
- f) Under this Agreement and in accordance with applicable guidance and regulations, the Manufacturer—
- i. Shall not be required to provide access to the maximum fair price under paragraph (c), with respect to the Selected Drug and maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed the Selected Drug at a covered entity described in section 340B(a)(4) of the Public Health Service Act, to such covered entity if the Selected Drug is subject to an agreement described in section 340B(a)(1) of such Act and the ceiling price (defined in section 340B(a)(1) of such Act) is lower than the maximum fair price for such selected drug; and
 - ii. Shall be required to provide access to the maximum fair price to such covered entity with respect to maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed the Selected Drug at such entity at such ceiling price in a nonduplicated amount to the ceiling price if such maximum fair price is below the ceiling price for the Selected Drug.
- g) In accordance with section 1193(c) of the Act and applicable guidance and regulations, information submitted to CMS under the Negotiation Program by the Manufacturer that is proprietary information of such Manufacturer, as determined by CMS, shall be used only by CMS or disclosed to and used by the Comptroller General of the United States to carry out such Negotiation Program, unless otherwise required by law.

III. Effective Date, Term and Termination

- a) This Agreement shall have an effective date of the date this Agreement is signed by both parties.
- b) The term of this Agreement shall be from the effective date until the termination date, which shall be the earlier of the first day that the Selected Drug is no longer a selected drug pursuant to CMS' determination in accordance with section 1192(c) of the Act and applicable guidance and regulations, or the date that the Agreement is terminated by either party in accordance with applicable guidance and regulations.
- c) Notwithstanding the termination of this Agreement, certain requirements and obligations shall continue to apply in accordance with applicable guidance and regulations.

IV. General Provisions

- a) This Agreement contains the entire agreement of the parties with respect to the subject matter of this Agreement and supersedes all prior oral and written representations, agreements, and understandings of the parties. If CMS and the Manufacturer reach agreement on a price for the Selected Drug pursuant to section II(a) or II(b) of this Agreement, CMS and the Manufacturer shall execute an addendum setting forth the price for the Selected Drug that will apply for purposes of this Agreement.

- b) CMS retains authority to amend this Agreement to reflect changes in law, regulation, or guidance. When possible, CMS shall give the Manufacturer at least 60-day notice of any change to the Agreement.
- c) Any notice required to be given by either party pursuant to the terms and provisions of this Agreement shall be sent by email. CMS shall provide the appropriate email address for notice in guidance, rulemaking, or other publications. The Manufacturer shall provide the appropriate email address(es) for notice to CMS in a form and manner specified by CMS.
- d) Nothing in this Agreement shall prohibit the Manufacturer from transferring the Selected Drug and obligations of this Agreement to another entity in accordance with applicable guidance and regulations.
- e) Nothing in this Agreement shall limit the Manufacturer from providing access under the Medicare program to a price lower than the price determined pursuant to this Agreement.
- f) In signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS' views, and makes no representation or promise beyond its intention to comply with its obligations under the terms of this Agreement with respect to the Selected Drug. Use of the term "maximum fair price" and other statutory terms throughout this Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms.
- g) Nothing in this Agreement shall be construed to require or authorize the commission of any act contrary to law. If any provision of this Agreement is found to be invalid by a court of law with competent jurisdiction, this Agreement will be construed in all respects as if any invalid or unenforceable provisions were eliminated, and without any effect on any other provision.
- h) No failure by any party to insist upon the strict performance of any requirement, obligation or condition of this Agreement shall constitute a waiver of any such requirement, obligation or condition.
- i) This Agreement shall be construed in accordance with Federal law and any ambiguities shall be interpreted in the manner that best effectuates the statute. Any litigation relating to this Agreement, to the extent that jurisdiction and a cause of action would otherwise be available for such litigation, shall be resolved in Federal court. Actions by the Manufacturer for damages are not permitted pursuant to this Agreement, and the Manufacturer's remedies for any breach are limited to termination of the Agreement or other action consistent with applicable statutes, regulations, or guidance.
- j) CMS and the Manufacturer acknowledge and agree that in accordance with section 1197 of the Act and 26 U.S.C. § 5000D, the Manufacturer may be subject to civil monetary penalties and an excise tax, as applicable, for failure to meet the requirements of the Negotiation Program, including violations of this Agreement.
- k) Neither party shall be liable for failure to perform its obligations under this Agreement if such failure is occasioned by a contingency beyond such party's reasonable control, including, but not limited to, lockouts, riots, wars, fires, floods or storms (a "Force Majeure Event"). A party claiming a right to excused performance under this section shall promptly notify the other party in writing of the extent of its inability to perform, which notice shall specify the Force Majeure Event that prevents such performance and include a timeline for remediation. The party failing to perform shall use reasonable efforts to avoid or remove the cause of the Force Majeure Event and shall resume performance under the Agreement promptly upon the cessation of the Force Majeure Event.

V. Signatures

FOR THE MANUFACTURER

A. By signing this Agreement, the Manufacturer agrees to abide by all provisions set forth in this Agreement and acknowledges having received notice of potential penalties for violation of the terms of the Agreement.

B. The undersigned individual hereby attests that he or she is authorized by the Manufacturer to execute this Agreement with regard to the Selected Drug and to legally bind the Manufacturer on whose behalf he or she is executing the Agreement to all terms and conditions specified herein. The undersigned individual further attests that he or she has obtained access in the CMS Health Plan Management System (CMS HPMS) as an authorized representative to be signatory for the Manufacturer and that the individual's CMS HPMS access credentials contain the same information regarding the undersigned individual as the information set forth below.

By:

Print Name: _____

Signature: _____

Title: _____

Date: _____

P-Number: _____

Manufacturer Address: _____

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES

By:

Print Name: _____

Signature: _____

Title: _____

Date: _____

Addendum 1: Negotiated Maximum Fair Price

MEDICARE DRUG PRICE NEGOTIATION PROGRAM AGREEMENT
NEGOTIATED MAXIMUM FAIR PRICE ADDENDUM
(hereinafter referred to as the “Addendum”)

Between

the Centers for Medicare & Medicaid Services (CMS), pursuant to delegated authority of the Secretary of Health and Human Services

And

[Full Name of Manufacturer]
(hereinafter referred to as the “Manufacturer”)

For

[Name of Selected Drug]
(hereinafter referred to as the “Selected Drug”)

WHEREAS, the Manufacturer has in effect a Medicare Drug Price Negotiation Agreement (the “Agreement”), which the Manufacturer entered into with CMS on [Date], to negotiate to determine a price (referred to as “maximum fair price” in the Social Security Act (“the Act”)) for the Selected Drug under the Negotiation Program; and

WHEREAS, the Manufacturer and CMS have engaged in negotiation of the price for the Selected Drug in accordance with the negotiation process set forth in section 1194 of the Act and applicable guidance and regulations; and

WHEREAS, the Manufacturer and CMS now agree to a price for the Selected Drug, as published by CMS in accordance with section 1195(a) of the Act and updated in accordance with sections 1195(b) and 1196(a)(2) of the Act and applicable guidance and regulations, which will apply for purposes of the Agreement;

NOW THEREFORE, the Manufacturer and CMS agree to this Addendum, such that the following terms are hereby incorporated as part of the Agreement:

- a) The parties agree to a price of [\$] for the Selected Drug per 30-day equivalent supply, weighted across dosage forms and strengths.
- b) The parties agree that the price set forth in clause (a) shall apply to the dosage forms and strengths of the Selected Drug as identified on the list of National Drug Codes (NDCs) maintained by CMS as may be updated with information from the manufacturer in accordance with section 1193 of the Act and applicable guidance and regulations.
- c) The parties agree that the price set forth in clause (a), which in accordance with section 1196(a)(2) of the Act and applicable guidance and regulations is computed and applied by CMS across the different strengths and dosage forms of the Selected Drug as set forth

in clause (b), is binding and shall apply as specified in the Agreement and in accordance with the Act and any applicable guidance and regulations.

Signatures

FOR THE MANUFACTURER

A. By signing below, the Manufacturer agrees to this Addendum to the Agreement and acknowledges having received notice of potential penalties for violation of the terms of the Addendum and the Agreement.

B. The undersigned individual hereby attests that he or she is authorized by the Manufacturer to execute this Agreement with regard to the Selected Drug and to legally bind the Manufacturer on whose behalf he or she is executing the Agreement to all terms and conditions specified herein. The undersigned individual further attests that he or she has obtained access in the CMS Health Plan Management System (CMS HPMS) as an authorized representative to be signatory for the Manufacturer and that the individual’s CMS HPMS access credentials contain the same information regarding the undersigned individual as the information set forth below.

By:

Print Name: _____

Signature: _____

Title: _____

Date: _____

P-Number: _____

Manufacturer Address: _____

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES

By:

Name: _____

Signature: _____

Title: _____

Date: _____

Addendum 2: Renegotiated Maximum Fair Price

MEDICARE DRUG PRICE NEGOTIATION PROGRAM AGREEMENT
RENEGOTIATED MAXIMUM FAIR PRICE ADDENDUM
(hereinafter referred to as the “Addendum”)

Between

the Centers for Medicare & Medicaid Services (CMS), pursuant to delegated authority of the Secretary of Health and Human Services

And

[Full Name of Manufacturer]
(hereinafter referred to as the “Manufacturer”)

For

[Name of Selected Drug]
(hereinafter referred to as the “Selected Drug”)

WHEREAS, the Manufacturer has in effect a Medicare Drug Price Negotiation Agreement (the “Agreement”), which the Manufacturer entered into with CMS on [Date], to negotiate to determine a price (referred to as “maximum fair price” in the Social Security Act (“the Act”)) for the Selected Drug under the Negotiation Program and agreed to such a price on [Date(s)]; and

WHEREAS, the Manufacturer and CMS have engaged in renegotiation of the price for the Selected Drug in accordance with the renegotiation process set forth in section 1194 of the Act and applicable guidance and regulations; and

WHEREAS, the Manufacturer and CMS now agree to a renegotiated price for the Selected Drug, as published by CMS in accordance with section 1194(f)(4) of the Act and updated in accordance with sections 1194(f)(4) and 1196(a)(2) of the Act and applicable guidance and regulations, which will apply for purposes of the Agreement; and

NOW THEREFORE, the Manufacturer and CMS agree to this Addendum, such that the following terms are hereby incorporated as part of the Agreement:

- a) The parties agree to a price of [\$] for the Selected Drug per 30-day equivalent supply, weighted across dosage forms and strengths.
- b) The parties agree that the price set forth in clause (a) shall apply to the dosage forms and strengths of the Selected Drug as identified on the list of National Drug Codes (NDCs) maintained by CMS as may be updated with information from the manufacturer in accordance with section 1193 of the Act and applicable guidance and regulations.
- c) The parties agree that the price set forth in clause (a), which in accordance with section 1196(a)(2) of the Act and applicable guidance and regulations is computed and applied by CMS across the different strengths and dosage forms of the Selected Drug as set forth in clause (b), is binding and shall apply as specified in the Agreement and in accordance with the Act and any applicable guidance and regulations.

Signatures

FOR THE MANUFACTURER

A. By signing this, the Manufacturer agrees to this Addendum to the Agreement and acknowledges having received notice of potential penalties for violation of the terms of the Addendum and the Agreement.

B. The undersigned individual hereby attests that he or she is authorized by the Manufacturer to execute this Agreement with regard to the Selected Drug and to legally bind the Manufacturer on whose behalf he or she is executing the Agreement to all terms and conditions specified herein. The undersigned individual further attests that he or she has obtained access in the CMS Health Plan Management System (CMS HPMS) as an authorized representative to be signatory for the Manufacturer and that the individual's CMS HPMS access credentials contain the same information regarding the undersigned individual as the information set forth below.

By:

Print Name: _____

Signature: _____

Title: _____

Date: _____

P-Number: _____

Manufacturer Address: _____

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES

By:

Name: _____

Signature: _____

Title: _____

Date: _____