

**MEMORANDUM OF UNDERSTANDING  
AMONG  
THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,  
GILEAD SCIENCES, INC.  
AND  
AMERISOURCEBERGEN CORPORATION**

**June 27, 2020**

This Memorandum of Understanding (“MOU”) is entered into as of the above date among the United States Department of Health and Human Services (“HHS”) through the Assistant Secretary for Preparedness and Response (“ASPR”), Gilead Sciences, Inc. (“Gilead”) and AmerisourceBergen Corporation, through its operating subsidiary (b)(4) (b)(4) (“Distributor”). HHS, ASPR, Gilead and Distributor are sometimes referred to hereafter collectively as the “Parties.”

**WHEREAS**, Distributor was appointed as the authorized distributor of Gilead’s investigational product remdesivir (the “Product”), for the doses of Product donated by Gilead to HHS through ASPR pursuant to a donation agreement between Gilead and HHS (“Product Donation Agreement”), for distribution as authorized pursuant to an Emergency Use Authorization (“EUA”) issued by the FDA on May 1, 2020 or pursuant an investigational new drug application authorized by the FDA;

**WHEREAS**, pursuant to the terms of the EUA as originally granted, or as subsequently amended, the Product will be distributed and available for purchase by administering hospitals and other designated healthcare providers (“Providers”), consistent with the terms of the EUA; and

**WHEREAS**, the Parties desire to set forth the terms on which the Product will be made available by Gilead to Distributor for sale to Providers, pursuant to the EUA, recognizing that there is separate distribution agreement between Gilead and the Distributor with respect to the Product.

**NOW, THEREFORE**, the Parties agree as follows:

**1. Purpose.** The purpose of this MOU is to set forth the terms for the Parties to work collaboratively with one another and with State and US Territory health authorities (“Authorities”) to ensure the fair and equitable commercial distribution of the Product as a treatment for patients diagnosed with Covid-19. Further details of the sale and distribution of Product to Providers will be negotiated between Distributor and Gilead in good faith promptly following execution of this MOU (“Gilead/Distributor Agreement”).

**2. Legal Authorities and Representations.** This MOU is authorized under Sections 301 and 311 of the Public Health Service Act. HHS represents that the activities undertaken by the Parties under this MOU and under the Gilead/Distributor Agreement to treat patients with COVID-19 present unusually hazardous risks to Distributor and Gilead given the spread of the disease and the uncertain need for the quantities of the Product set forth below.

**3. Product Availability.** Gilead shall use commercially reasonable efforts to manufacture and make available for purchase in the U.S. and U.S. Territories the following quantities of Product during the months of July, August and September, 2020, which represents 90% of the monthly anticipated available global supply, except for July number which is 100% of the anticipated available global supply, excluding clinical trial amounts for all months:

- **July** = 94,200 treatment courses (6.25 vials per treatment course)
- **August** = 174,900 treatment courses (6.25 vials per treatment course)
- **September** = 232,800 treatment courses (6.25 vials per treatment course)

Thirty days prior to the beginning of each calendar month (other than July), ASPR shall notify Gilead and Distributor in writing of the amount of Product from the maximum quantities described above that it will allocate to Providers during that month (“Allocation Commitment”). For purposes of this Agreement, the Allocation Commitment for July will be deemed 94,200 treatment courses and for August will be deemed 174,900 treatment courses (6.25 vials per treatment course).

If the Allocation Commitment for any month is less than the amount committed by Gilead above for that month, Gilead shall have the right to allocate the leftover Product for that month outside the United States or for other uses as deemed necessary by Gilead. To the extent Providers do not purchase the full amount of Product allotted to them by Authorities for a particular two-week period, the Parties shall confer and determine whether Gilead should attempt to reallocate the leftover Product outside the United States. In the case where the Parties determine to reallocate leftover Product outside the United States, Distributor shall be under no obligation to distribute, sell or otherwise handle any such extra Product.

Gilead does not guarantee hereunder that it will have sufficient Product to meet demand, and nothing in this MOU shall be interpreted as providing such guarantee. Due to production schedules, Gilead will supply Product as it becomes available on a weekly basis, up to the monthly Allocations Commitments.

**4. Distribution of Product Supply.** Subject to the availability of Product, each Allocation Commitment, and the provisions of Sections 5, 6 and 7 below, Distributor will sell and ship the Product to Providers identified by the Authorities. ASPR will direct the Authorities

to provide such information to Distributor regardless of whether the Provider is currently a customer of Distributor, subject to the following:

- ASPR will set allocation quantities for each Authority for sale to Providers; and
- ASPR will ensure that the Authorities provide information to Distributor no less frequently than bi-weekly regarding the allocated quantities of Product to be shipped to Providers, including, but not limited to, identifying specific Providers, applicable quantities and the additional information set forth on Appendix 1 hereto.

The Parties acknowledge and agree that Gilead and Distributor shall have no responsibility or discretion with respect to all such identification of Providers, direction of Product or related decisions by ASPR or the Authorities. Distributor will work directly with ASPR, in consultation with Gilead, to address any questions or concerns related to the direction of distribution of Product to particular Providers. Unless otherwise agreed by the Parties under Section 3, if a Provider elects not to receive its allocated share of Product, Distributor shall notify the applicable Authority and ASPR promptly and the subject Product shall be re-allocated by the Authority, in coordination with ASPR, pursuant to the foregoing.

**5. Product Cost and Distribution Markup; Payment Terms.** Gilead agrees that, throughout the term of this MOU and the Gilead/Distributor Agreement, the Wholesale Acquisition Cost (WAC) of each vial of Product shall be \$520. Gilead and Distributor agree that, throughout the term of this MOU and the Gilead/Distributor Agreement: (a) Gilead will sell the Product at WAC, (b) Distributor will sell the Product to Providers at a price no higher than WAC, provided that Distributor may impose service fees or finance charges on Providers as set forth in Section 6, and (c) unless a Provider has other payment terms with Distributor, Providers shall be required to pay Distributor for the Product using Distributor's standard Payment Terms.

(b)(4)

(b)(4) Distribution fees, payment terms and other obligations between Gilead and Distributor, including reporting and related matters, will be set forth in the Gilead/Distributor Agreement. (b)(4)

(b)(4)



**6. Eligibility of Providers; Courtesy Billing.** Distributor's obligation to sell Product to a Provider is subject to a Provider meeting Distributor's commercially reasonable qualifications, including creditworthiness, licensure and other qualifications generally applied in the wholesale distribution industry. Distributor, in its reasonable discretion, may determine whether to extend, withhold or suspend the credit of any Provider or whether to impose any service fees or finance charges on any Provider. If a Provider cannot meet Distributor's commercially reasonable qualifications, the Parties shall confer in good faith following notice from Distributor regarding appropriate measures for such Provider. Providers will be required to agree that they will (a) use all Products for their "own use" (as defined legally) and (b) not distribute Products to any other person, including distributors, re-packagers or suppliers. The Parties acknowledge that Product returns will be handled in accordance with the Gilead/Distributor Agreement and the Gilead/Distributor Agreement shall reflect a provision providing that, from and after October 15, 2020, (b)(4)

(b)(4)

(b)(4) Certain Providers that are currently customers of Distributor may request Distributor to invoice the Provider through the Provider's full-line wholesaler, AmerisourceBergen Drug Corporation ("ABDC"), an affiliate of Distributor. In these circumstances, Distributor will ship the Product directly to the Provider and invoice ABDC for the sale, and ABDC will bill the Provider for the sale. Gilead and HHS and ASPR acknowledge that Distributor may engage in courtesy billing transactions under the MOU or Gilead/Distributor Agreement.

**7. Unpurchased Allocated Product and Reservation of Government's Right to Procure.** In the event that Gilead is unable to sell Excess Product (as defined below), to one or more purchasers other than Distributor after having offered to sell such Excess Product to governments outside the United States, then HHS agrees to indemnify Gilead, pursuant to Section 301(a)(7) of the Public Health Service Act, for the losses associated with the Excess Product at \$390 per vial (i.e., the Federal Supply Schedule rate per vial), the global net price to governments established by Gilead ("Government Per Vial Price"). The loss associated with said Excess Product is equal to the amount determined by multiplying the Government Per Vial Price by the number of vials of Product comprising the Excess Product Amount (as defined below). Product will be considered Excess Product Amount and subject to indemnification only if Gilead or Distributor has not otherwise sold the Product to one or more purchasers on or before October 31, 2020, as further described in the definition of "Excess Product Amount". In lieu of HHS's indemnification, in whole or in part, HHS reserves the right, at its sole discretion, to procure any or all the Excess Product from Gilead at the Government Per Vial Price but, in such event, neither Distributor nor Gilead shall be under any obligation to distribute, sell or otherwise handle any such purchased Excess Product.

“Excess Product” shall mean treatment courses subject to the Allocation Commitments for August and September that remains unsold either by the Distributor to Providers or Gilead to ex-US purchasers as of September 30, 2020.

“Excess Product Amount” shall mean the lesser of (a) 145,000 treatment courses of Product and (b) the amount calculated as follows:

Scenario	Calculation conducted on or after November 1, 2020
Amount Sold in August/September is greater than 250,000 treatment courses:	Excess Product Amount equals (A) the aggregate number of treatment courses subject to the Allocation Commitment for August and September, less (B) the number of treatment courses sold by Distributor to Providers or by Gilead to ex-US purchasers, in each case through October 31, 2020.
Amount Sold in August/September is less than or equal to 250,000 treatment courses:	Excess Product Amount equals (A) The aggregate number of treatment courses subject to the Allocation Commitment for August and September, less (B) 250,000 treatment courses, less (C) the number of treatment courses sold by Distributor to Provider or Gilead to ex-US purchasers, in each case from October 1 through October 31.

**8. DSCSA.** Notwithstanding any exception or exemption that may be permitted upon agency enforcement discretion or other authority, Distributor shall comply with all applicable Drug Supply Chain Security Act (DSCSA) requirements, in transacting and distributing the Product, including ensuring each transaction under this Agreement includes Transaction Information, Transaction Statement, and Transaction History as defined by DSCSA.

**9. Product Handling.** Distributor shall at all times handle, maintain, store, transport, deliver and/or otherwise manage and distribute the Product in accordance with its handling and storage requirements (as set forth in the special handling and storage requirements of the Product Information sheet), and in accordance with industry codes of conduct and all laws, ordinances, regulations, rules, administrative directions and practices applicable to the handling, maintenance, storage, transport, sale and distribution of pharmaceuticals applicable to Distributor. In the event Distributor has not handled, maintained, stored, transported, delivered and/or otherwise managed the Product in accordance with this section or Gilead’s written instructions, Distributor shall notify Gilead within five (5) Business Days of such failure and shall destroy such Product in accordance with all applicable laws, ordinances, regulations, rules, administrative directions and practices. Distributor shall ensure the Product distributed by it includes all information required under the EUA that is provided by Gilead to Distributor (including without limitation the Product Fact Sheet). Distributor may not substitute another product for ordered Product for any reason.



**10. Liability Protection and Preemption.** HHS acknowledges that the Product is a “covered countermeasure” under the HHS Secretary’s Declaration issued pursuant to the Public Readiness and Emergency Preparedness Act (PREP Act), effective February 4, 2020, for certain medical products to be used against COVID-19. See 85 Fed. Reg. 15,198, 15,202 (March 17, 2020) as amended; *see also* Pub. L. No. 109-148, Public Health Service Act § 319F-3, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e. The immunity provisions and pre-emption protections provided by the PREP Act extend to the participation of Gilead and Distributor in this MOU and the Gilead/Distributor Agreement. Additionally, Distributor will disclaim all warranties and liability regarding the Product in terms established with Providers. HHS represents that the distribution protocol described in the MOU is consistent with the EUA for the Product.

**11. Miscellaneous.** Promptly following execution of this MOU, HHS shall reimburse Distributor, through contract or other vehicle as reasonably determined by the Government, the amount of \$15,000 in respect of special handling and shipping fees (airplane rental) incurred by Distributor in connection with its distribution of Product under the Product Donation Agreement.

**12. Notices.** (b)(4)

(b)(4)

**13. Commencement, Modification, and Termination.** The respective obligations of the Parties shall commence on the execution of this MOU. This MOU may be modified by written agreement of the Parties. It is expected that this MOU and the Gilead/Distributor Agreement shall remain in effect until September 30, 2020, unless otherwise agreed to in writing by the Parties. Following written consent of Gilead, not to be unreasonably withheld or delayed, ASPR may adjust the treatment course quantity for the month of September 2020 specified in paragraph 3 of this MOU and will provide notice to the parties on or before August 14, 2020 with respect to such adjustment. This MOU does not amend the Product Donation Agreement in any respect.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Parties have executed this MOU as of the date first written above.

FOR HHS/ASPR

(b)(6)

Robert P. Kadlec, MD  
Assistant Secretary for  
Preparedness and Response

FOR AMERISOURCEBERGEN/

(b)(4)

(b)(6)

FOR GILEAD SCIENCES, INC.

(b)(6)

## APPENDIX 1

### RDV STATE/HOSPITAL SUBMISSION REQUIREMENTS

These data elements are required:

- (1) Hospital Ship To Name
- (2) Ship to Address
- (3) City
- (4) State
- (5) Zip
- (6) Lyophilized powder Cases (57527)- AMBIENT
- (7) Lyophilized powder Eaches (57527)- AMBIENT
- (8) Liquid Solution Cases (57251)- REFRIGERATED
- (9) Liquid solution Eaches
- (10) Point of Contact First Name
- (11) Point of Contact Last Name
- (12) Telephone
- (13) Email
- (14) Notes

These data elements will be provided by (b)(4) representatives:

- (15) (b)(4) Account# (input by (b)(4))
- (16) Assigned Sales Rep (input by (b)(4))

See attached PDF for suggested formatting, which the Parties may adapt for mutually convenient purposes.



Hospital Ship To Name	Ship To Address	City	State	Zip	Lyophilized powder Cases (57527)- AMBIENT	Lyophilized powder Cases (57527)- AMBIENT	Liquid Solution Cases (57251)- REFRIGERATED	Liquid Solution Cases (57251)- REFRIGERATED	Point of Contact First Name	Point of Contact Last Name	Telephone	Email	Notes	Account (input by)	Assigned Sales Rep (input by)
														hy4	hy4