IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE

In re:	:	
	:	Chapter 11
	:	
INSYS THERAPEUTICS, INC., *et al*.,	:	
	:	Case No. 19-11292 (KG)
	:	
Debtors.	:	Extended Obj. Deadline:[1]
	:	August 9, 2019 by 4 p.m.

OBJECTION OF THE UNITED STATES TO NOTICE OF CURE COSTS AND POTENTIAL ASSUMPTION AND ASSIGNMENT OF EXECUTORY CONTRACTS AND UNEXPIRED LEASES IN CONNECTION WITH SALE

The United States, on behalf of the United States Department of Health and Human Services ("HHS") acting through its designated component, the Centers for Medicare & Medicaid Services ("CMS"), the Defense Health Agency ("DHA"), and the United States Department of Veterans' Affairs ("VA"), objects to the above-referenced debtors' (the "Debtors") Notice of Cure Costs and Potential Assumption and Assignment of Executory Contracts and Unexpired Leases in Connection with the Sale [Dkt. No. 263] (the "Cure Notice") and the Supplemental Notice of Cure Costs and Potential Assumption and Assignment of Executory Contracts and Unexpired Lease in Connection with the Sale [Dkt. No. 388] (the "Supplemental Cure Notice," collectively the "Cure Notices"). In support of its objection, the United States respectfully states as follows:

[1] Pursuant to on-going discussion between the United States and the Debtors over the issues raised herein, the Debtors granted the United States three extensions of time to file a response to the Cure Notice. Because of the complexities of the issues, discussions between the parties continue and the United States files this Objection simply as a protective measure.

BACKGROUND

1. The Debtors filed for chapter 11 bankruptcy protection in the United States Bankruptcy Court for the District of Delaware on June 10, 2019 (the "Petition Date").

2. As described more fully in the Debtors' first day pleadings, before the Petition Date, the Debtors participated in certain government rebate programs that provide discounted prescriptions to qualified insured-patients, including rebate programs with Medicaid and Medicare Part D.

3. Medicaid offers prescription drug benefits to Medicaid beneficiaries. For Medicaid to cover a drug, the drug's manufacturer must participate in the Medicaid Drug Rebate Program ("Medicaid Rebate Program"), *see* 42 U.S.C. § 1396r-8, and enter into a Medicaid National Drug Rebate Agreement ("Medicaid Rebate Agreement") with the Secretary of HHS, *see* 42 U.S.C. §§ 1396b & 1396r-8(a). Under the Medicaid Rebate Agreement, manufacturers must rebate the States for drugs used by Medicaid beneficiaries, rebating to the States directly on a quarterly basis. 42 U.S.C. § 1396r-8(b)(1). Besides entering into a Medicaid Rebate Agreement, drug manufacturers must also, among other things, enter into a Master Agreement with the VA for the Federal Supply Schedule to participate in the Medicaid program. *See* Act at § 1927(a)(5)-(6); 38 U.S.C. § 8126. All fifty States and the District of Columbia cover prescription drugs under the Medicaid Rebate Program.

4. Medicare also offers prescription drug benefits to Medicare beneficiaries through the Medicare Part D Program. Under Medicare Part D, Medicare beneficiaries choose a private-insurance Part D sponsor ('Part D Plan Sponsors") to provide

prescription drug benefits. For a drug to be covered by the Medicare Part D program, the drug's manufacturers must, among other things, enter into a "Medicare Coverage Gap Discount Program Agreement" with CMS. *See* 42 C.F.R. §§ 423.2310, 423.2315. Under this agreement, a manufacturer agrees to reimburse Part D Plan Sponsors a certain percentage of a drug's price under certain circumstances within thirty-eight days of being invoiced. CMS guarantees payments to the Part D Plan Sponsors, and may impose civil money penalties on manufacturers who fail to pay such reimbursements. 42 C.F.R. § 423.2340.

5. The Department of Defense ("DOD") also operates pharmacy benefit programs, including the TRICARE Retail Pharmacy Program. 10 U.S.C. § 1074g(a)(2)(E)(ii). The TRICARE Retail Pharmacy Program ensures manufacturers' adherence to federal pharmaceutical pricing standards for TRICARE beneficiaries. 10 U.S.C. § 1074g(f). To enforce the federal pricing standards and have a drug available under the TRICARE Retail Pharmacy Program, DHA enters into a "Retail Refund Pricing Agreement" with the drug's manufacturer. Under the Retail Refund Pricing Agreement and the applicable regulations, a manufacturer must rebate DHA the difference between the "non-Federal average manufacturing prices" and the Federal Price Ceiling Standards within a specific period of time after DHA submits data on the drug's use by TRICARE beneficiaries. 32 C.F.R. §§ 199.21(q)(2) & (q)(3).

6. Pursuant to the Bid Procedures Order,[2] on July 2, 2019, the Debtors filed the Cure Notice. The Cure Notice lists 19 purported federal "executory contracts" that

[2] Order (A) Approving Bidding Procedures For Sale Of Debtors' Assets, (B) Scheduling Auction For And Hearing To Approve Sale Of Debtors' Assets, (C) Approving Form And Manner Of Notice Of Sale, Auction, And Sale Hearing, (D) Approving Assumption And Assignment

the Debtors may seek to assume and assign as part of the sales process (the "Initial Federal Contracts"). The Debtors list a zero dollar ($0) cure amount for every Initial Federal Contract, except for the Debtors' "Medicaid National Drug Rebate Agreement." The Debtors list a $1,611,131 cure amount (the "Proposed Medicaid Cure Amount") for their Medicaid National Drug Rebate Agreement ("Insys Medicaid Rebate Agreement"). *Id.*

7. On August 2, 2019, the Debtors filed the Supplemental Cure Notice. In the Supplemental Cure Notice, the Debtors list 16 additional purported federal "executory contracts," including its Medicare Coverage Gap Discount Program Agreement ("the Insys Medicare Gap Agreement"), that they may seek to assume and assign in connection with the sale of their assets ("Additional Federal Contracts" and collectively with the Initial Federal Contracts, "Federal Contracts"). The Debtors list a zero dollar ($0) cure amount for each Additional Federal Contracts.

OBJECTION

8. The United States objects to the Cure Notices and the potential assumption and assignment of the Federal Contracts for four reasons. First, the cure amounts listed for certain Federal Contracts are incorrect. Second, the Debtors may not assume and assign the Federal Contracts without the United States' explicit consent. Third, any Successful Bidder or purchaser who takes assignment of the Federal Contracts that are subject to the Federal Acquisition Regulations ("FAR") must follow the FAR novation process, which requires assumption of all obligations and liability. Fourth, the Insys Medicaid Rebate Agreement and the Insys Medicare Gap Agreement also require any

Procedures, And (E) Granting Related Relief [Dkt. No. 210]. Capitalized terms not otherwise defined herein shall have the same meaning ascribed to them in the Bid Procedures Order.

Successful Bidder or purchaser to take the burdens imposed under those agreements. Accordingly, the United States cannot be bound by any amounts included (or not included) in the Cure Notices because the assumption and assignment of the Federal Contracts requires a Successful Bidder or purchaser to assume successor liability with respect to any amounts that may be owed under such contracts regardless of when the amounts become due or known.

A. The Cure Notices List Incorrect Cure Amounts for Certain Federal Contracts.

9. Since the filing of the Cure Notices, the Government has diligently attempted to reconcile its records with the Cure Notices to determine whether any outstanding debts are owed under the various government rebate programs, including the Medicaid Rebate Program.

10. As of the date of this filing, the United States confirms that the Debtors have FSS Contract Number V797D30295 with the VA (the "VA Contract") that runs through January 2020, and the United States had determined that no cure is currently due.

11. Although DHA confirmed that the Debtors' Retail Refund Pricing Agreement for Subsys (the "DHA Contract") that has not expired, the Debtors currently owe $232,971.02 in refunds for amounts that DHA paid for Subsys above the Federal Ceiling Price Standards during the first quarter of 2019. *See* Exhibit A.[3]

[3] Although counsel for the Government notified Debtors' counsel of the amount due DHA, and asked whether such amount would be paid pursuant to the final order entered July 3, 2019 [Dkt. No. 232] authorizing the Debtors to maintain and administer its customer programs, promotions, and practices, and honor any related prepetition obligations consistent with past practices in the ordinary course, the Government has received no response.

12. The Government cannot confirm the validity of the Proposed Medicaid Cure Amount. The Medicaid Rebate Program and the terms of the Insys Medicaid Rebate Agreement require the Debtors to directly pay the States any applicable rebate. Whether the Debtors properly noticed every State's (and the District of Columbia's) Medicaid agency of the Proposed Medicaid Cure Amount and notified each State of the proposed cure amount due a particular State is unclear. In an effort to determine amounts due the States under the Insys Medicaid Rebate Agreement, the Government requested that Debtors provide information about the Insys Medicaid Rebate Agreement and the Proposed Medicaid Cure Amount, but the Debtors have provided no additional information. Therefore, the Government cannot confirm the validity or amount of the Proposed Medicaid Cure Amount.

13. Finally, as of this filing, CMS confirms that the Debtors' owe no amounts to CMS under the Insys Medicare Gap Agreement.

B. The Federal Contracts Cannot Be Assumed and Assigned without the United States' consent.

14. Even if the Debtors make the appropriate cures, the United States objects to the assumption and assignment of the Federal Contracts without its consent. Section 365(c)(1) of the Bankruptcy Code prohibits the Debtors from assuming and assigning executory contracts when "applicable law excuses a party, other than the debtor, to such a contract from accepting performance from . . . an entity other than the debtor or debtor in possession" without the non-debtor's consent. 11 U.S.C. § 365(c)(1). The Anti-Assignment Act expressly provides:

> The party to whom the Federal Government gives a contract or order may not transfer the contract or order, or any interest in the contract or order, to another party. A purported transfer in violation of this subsection annuls

> the contract or order so far as the Federal Government is concerned, except that all rights of action for breach of contract are reserved to the Federal Government.

41 U.S.C. § 6305 (emphasis added). Thus, the Anti-Assignment Act constitutes applicable law that excuses the United States from accepting performance of the Federal Contracts from anyone but the Debtors for purposes of section 365(c)(1*). In re West Elecs*., 852 F.2d 79, 83 (3d Cir. 1988). Unless the United State consents, this Court must prohibit the Debtors from assuming and assigning the Federal Contracts.

C. Federal Contracts Subject to the FAR Require Novation.

15. Along with obtaining the United States' consent, a Successful Bidder must complete the multi-step regulatory novation process under the FAR and execute a novation agreement with the United States for the VA Contract, a contract subject to the FAR.[4] *See* 48 C.F.R. § 42.1204(a). First, the purchaser must submit a written request to the responsible contracting officer. 48 C.F.R. § 42.1203(a). Next, the responsible contracting officer must determine whether recognizing the purchaser as a successor in interest is in the United States' best interest. *Id.* at § 42.1203(c). To make this determination, the contracting officer must be privy to certain information about the proposed transfer, including, but not limited to: (i) the transferee's responsibility under FAR Subpart 9.1 ("Responsible Prospective Contractors"), (ii) whether any significant organizational conflicts of interest exist under FAR Subpart 9.5 ("Organizational and Consultant Conflicts of Interest"), (iii) evidence of the transferee's capability to perform;

[4] The United States reserves its rights to object to the assumption and assignment of any contract it later determines is subject to the FAR to the extent the Debtors wish to assume and assign the contract without completing the novation process outlined here.

and (iv) evidence that any security clearance requirements have been met. *Id.* at §§ 42.1203(c)(2); 42.1204.

16. As a successor in interest under the FAR, a Successful Bidder generally assumes all of the Debtors' obligations under the contract. *Id.* at § 42.1204 (h)(1). As a result, novation agreements must include a statement indicating that "[t]he Transferee has assumed all obligations and liabilities of the Transferor under the contracts by virtue of the above transfer." *Id.* at § 42.1204(i)(a)(4). *See also id*. at § 42.1204(i)(b)(2) ("The Transferee agrees to be bound by and to perform each contract in accordance with the conditions contained in the contracts. The Transferee also assumes all obligations and liabilities of, and all claims against, the Transferor under the contracts as if the Transferee were the original party to the contracts.").

17. Because the novation process requires that a Successful Bidder assume "all obligations and liabilities," the Government cannot be bound by the amounts included in Cure Notices. A Successful Bidder will have to assume successor liability with respect to the VA Contract. Accordingly, this Court should deny the assumption and assignment of the VA Contract and, instead, authorize the Debtors to novate the VA Contract in accordance with the FAR and with the United States' consent.

D. Any Successful Bidder Must Take the HHS Federal Contracts with those Contracts' Burdens.

18. The Debtors cannot assume and assign and no Successful Bidder can take the Insys Medicaid Rebate Agreement's or the Insys Medicare Gap Agreement's benefits without their burdens. The Insys Medicaid Rebate Agreement, which is attached as Exhibit B, provides that: "In the event of a transfer in ownership of the manufacturer, this agreement and any outstanding rebate liability are automatically assigned to the new

owner subject to the conditions as set forth in section 1927 of the Act." Ex. B at 8. Likewise, the Insys Medicare Gap Agreement, which is attached as Exhibit C, requires that, if ownership is transferred, "all terms and conditions of th[e] Agreement remain in effect." Ex. C at Art. XI,(b). *See also* 83 Fed. Reg. 12770, 12786 (Mar. 23, 2018) (final notice announcing that under HHS Rebate Agreements, assignment of said agreements following change in ownership requires new owner to assume "any outstanding rebate liability"); 42 C.F.R. § 423.2315(a) (authorizing HHS to establish model agreement governing HHS Discount Agreements); 75 Fed. Reg. 29555, 29559 (May 26, 2010) (providing notice of terms of model agreement governing HHS Discount Agreements, including requirement that, upon assignment of said agreements following a change in ownership, "all terms and conditions of this Agreement remain in effect.").

19. The Bankruptcy Code prohibits the assumption and assignment of a contract's benefits without its burdens. Section 365 requires that an executory contract be assumed and assigned *cum onere* (*i.e.*, with all of its benefits *and* all of its burdens). *In re Fleming Cos.*, 499 F.3d 300, 307-08 (3d Cir. 2007) ("The debtor may not blow hot and cold. If he accepts the contract he accepts it *cum onere*. If he receives the benefits he must adopt the burdens. He cannot accept one and reject the other.") (citation, internal quotation marks, and alterations omitted); *University Med. Ctr. v. Sullivan* (*In re University Med. Ctr.*), 973 F.2d 1065, 1075 (3d Cir. 1992). To the extent the Debtors attempt to assume and assign the Insys Medicaid Rebate Agreement and the Insys Medicare Gap Agreement without those agreements' burdens, this Court should deny their assumption and assignment to a Successful Bidder.

CONCLUSION

20. Accordingly, based on the foregoing, the United States objects to the Cure Notices to the extent they limit amounts that may be owed under the Federal Contracts, including the Insys Medicaid Rebate Agreement, and asks this Court to deny the assumption and assignment of the Federal Contracts to the extent that they would be assumed and assigned without cure, consent, and compliance with applicable law. The United States reserves all rights with respect to the Cure Notices and its right to amend or supplement this Objection to the extent that additional amounts or other non-monetary obligations under the Federal Contracts become known.

21. By filing this Objection, the United States does not waive any other rights, claims, actions, defenses, setoffs, or recoupments to which it entitled, including its right to object to the assumption and assignment of the Federal Contracts, and all rights, claims, actions, defenses, setoffs, and recoupments are expressly preserved.

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Dated: August 9, 2019

Respectfully submitted,

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Assistant Attorney General

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EXHIBIT A

DEFENSE HEALTH AGENCY
OGC-C

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
HEALTH AFFAIRS
16401 EAST CENTRETECH PARKWAY
AURORA, CO 80011-9066

A20482 - Insys Therapeutics, Inc.
TIN# XX-XXXX7886
ATTN: Joe Hennessy
1333 South Spectrum Blvd, Suite 100
Chandler AZ 85286

Demand Letter Date:	July 22, 2019
Billing Period:	19Q1
Program:	Standard Discount
Utilization Date Principal:	$232,971.02
Principal Adjustment:	$0.00
Total Principal Due:	$232,971.02

To Mr. Hennessy:

The National Defense Authorization Act for Fiscal Year 2008 amended 10 U.S.C. § 1074g to extend Federal Ceiling Price (FCP) standards to Department of Defense (DoD) Retail Pharmacy Program prescriptions. On March 17, 2009, the DoD issued a Final Rule with an effective date of May 26, 2009, amending 32 C.F.R. § 199.21 to require pharmaceutical manufacturers to refund amounts paid by the DoD above the FCP. Defense Health Agency (DHA), formerly known as TRICARE Management Activity has determined that from January 1, 2019 through March 31, 2019 it made payments above the FCP for pharmaceuticals produced by Insys Therapeutics, Inc. (the Company) and is entitled to a refund of $232,971.02. This amount represents DHA's calculation of the debt and does not relieve the Company of its independent obligation to calculate and refund amounts owed pursuant to 32 C.F.R. § 199.21(q). Generally, failure to refund the total amount owed may subject the Company to liability pursuant to 31 U.S.C. § 3729, but we understand that on June 9, 2019, the Company filed for protection under chapter 11 of title 11 of the United States Code, and are mindful of the rights afforded the Company while it is in bankruptcy.

The Federal Claims Collection Act, beginning at 31 U.S.C. § 3701, requires federal agencies, including DHA, to collect funds owed to the United States arising out of the agency's activities. Further, pursuant to 31 U.S.C. § 3717, government agencies are required to collect interest on all delinquent debts at the rate of one percent (1%) per year. Interest charges will be waived if this debt is paid in full within 70 days from the date the utilization data were made available. The utilization data were made available on June 11, 2019; therefore the payment must be received by August 20, 2019 to avoid interest charges. If payment is not made within 70 days of the date the utilization data were made available, interest will accrue from the date of this letter. Additionally, federal agencies are required to assess a penalty charge, not to exceed six percent (6%) per year, upon any portion of amounts owed that are delinquent for more than 90 days, and assess administrative costs resulting from the delinquency.

The Company has the right to inspect and copy all records pertaining to this debt. If a manufacturer believes DHA's calculation of the debt is incorrect, the manufacturer may dispute the accuracy of the utilization data from which the debt was calculated in accordance with the procedures provided at 32 C.F.R. § 199.21 (q)(3)(iv). A refund obligation as to the amount in dispute will be deferred pending good faith efforts to resolve the dispute in accordance with procedures established by the Director, DHA. When the dispute is ultimately resolved, any refund owed relating to the amount in dispute will be subject to an interest charge from the date of this letter, consistent with 32 C.F.R. § 199.11.

Further, the Company may submit a request to compromise the debt and/or waive collection of interest, penalties and administrative costs pursuant to 32 C.F.R. § 199.11. During the pendency of any such request, the matter that is the subject of the request shall not be considered a failure of a manufacturer to honor an agreement for purposes of 32 C.F.R. § 199.21 (q)(4).

Although the Company is a debtor in bankruptcy, we understand that the United States Bankruptcy Court for the District of Delaware entered an order on July 3, 2019, authorizing the Company to maintain and administer its customer programs, promotions, and practices, and honor any related prepetition obligations in the ordinary course of business and consistent with past practice, as necessary and appropriate in the Debtors' business judgment (the Bankruptcy Court Order). If the Company can demonstrate that it is unable to refund the full amount in one payment, it may be afforded an opportunity to enter into a written agreement for payment of the debt. If the Company cannot pay the debt pursuant to the Bankruptcy Court Order, please have your attorneys contact our bankruptcy counsel, Mary A. Schmergel, U.S. Department of Justice, at 202-307-0183 or Mary.Schmergel@usdoj.gov.

To ensure that your payment is applied correctly, please include the following information:

1. The Program(s) for which the payment is being made (e.g. Standard Discount Program/MARR or Additional Discount Program/VARR)
2. The Calendar Quarter(s) for which the payment is to be applied
3. If payment is being made for multiple quarters, please indicate the amount to be applied to each respective quarter

To satisfy your debt immediately, please submit payment for the full amount on the TRICARE Retail Pharmacy Refunds form by using one of the payment methods below.

If paying by ACH or FED Wire through CREDIT GATEWAY:

FED Wires		ACH
TREAS NYC		CREDIT GATEWAY ACH RECEIVER
ABA/Routing #: 021030004	OR	ABA/Routing #: 051036706
Account #: 897000012002		Account #: 897000012002

If paying through Pay.gov, please use the link below:

https://www.Pay.gov
Labeler Code: Insys Therapeutics, Inc.
Program: SDP
Amount Due: $232,971.02
Invoice Number: A20482.B19Q1-F01.S

If paying by check or money order, please make payable to U.S.TREASURY/DHA and send to: (Please reference invoices)

Defense Health Agency
Attention: Accounting Officer
16401 E. Centretech Parkway
Aurora, CO 80011-9066

In addition, please include a signed statement indicating the amount owed per the Company's independent calculation with the following declaration:

I declare (or certify, verify, or state) under penalty of perjury, individually and on behalf of Insys Therapeutics, Inc. that the foregoing is true and correct.

Executed on [date],

by [signature]
[printed name]
[position]

Finally, please submit the supporting Reconciliation of Quarterly Utilization documentation on the TRICARE Retail Refunds Website (TRRWS) at https://refunds.ha.osd.mil/

For questions regarding the TRRWS or Defense Health Agency (DHA) Utilization Data, please contact:

Defense Health Agency Retail Refunds Team
(703) 681-8494
UFVARR_Requests@mail.mil

For questions regarding payments, please contact:

Contract Resource Management (CRM)
Defense Health Agency
(303) 676-3637
UFVARR_Requests@mail.mil

In order to avoid delays in processing future payments, please submit your Reconciliation of Quarterly Utilization on the TRRWS at the time of your payment.

Sincerely,

Katheryn A. Lima
Accounting Officer

*NOTICE TO DEBTORS PRESENTING CHECKS: When you provide a check as payment on your Defense Health Agency debt, you authorize us either to use information from your check to make a one time electronic fund transfer from your account or to process the payment as a check transaction. When we use information from your check to make an electronic fund transfer, funds may be withdrawn from your account as soon as the same day you make your payment. Privacy Act - A Privacy Act Statement required by 5 U.S.C. section 522a(e)(3) stating our authority for soliciting and collecting the information from your check, and explaining the purposes and routine uses which will be made of your check information, is available from our internet site at: https://www.pccotc.gov/pccotc/index.htm, or call toll free at 1-866-945-7920 (local number (Delaware) 302-324-6442, Military DSN 510-428-6824 (option 4, option 5, option 4) to obtain a copy by mail. Furnishing the check information is voluntary, but a decision not to do so may require you to make payment by some other method.

EXHIBIT B

Action Required: Updated Medicaid National Drug Rebate Agreement

On March 23, 2018, the Centers for Medicare & Medicaid Services (CMS) published in the Federal Register the final notice for the Medicaid National Drug Rebate Agreement (NDRA) CMS-2397-FN (Final Notice) that announced changes to the NDRA which is applicable as of the March 23, 2018 publication date. The updated NDRA incorporates legislative and regulatory changes that have occurred since the NDRA was last published on February 21, 1991, and also makes editorial and structural revisions, such as references to the updated Office of Management and Budget (OMB)-approved data collection forms and electronic data reporting. The NDRA reaffirms the manufacturer's responsibilities to correctly and consistently report drug product and pricing data to CMS in a timely manner, and refers to the statutory and regulatory citations for the definitions of single source, innovator multiple source, and non-innovator multiple source drugs.

As a currently participating manufacturer in the Medicaid Drug Rebate Program (MDRP), your company is required to complete (including the CMS-367d), sign, and submit to CMS a separate updated NDRA for each of your company's active labeler codes no later than September 30, 2018 in order to remain an active manufacturer in the program. If your company has multiple labeler codes that are currently active in the MDRP, a separate email notification will be sent for each labeler code to the Technical Contact on file with CMS.

The updated NDRA(s) can be printed, signed, and scanned or signed electronically and returned to CMS via an email attachment to drugrebateagreement@cms.hhs.gov. Manufacturers are no longer required to mail the original copy of the NDRA to CMS, rather they should retain the original copy of NDRA in their records. Once CMS has received and accepted a manufacturer's updated NDRA(s), the manufacturer will receive confirmation by e-mail, which will include a copy of their executed NDRA(s).

If your company does not complete (including the CMS-367d), sign, and return an NDRA before the deadline of September 30, 2018, please be advised that the Final Notice served as written notice of good cause to terminate your current rebate agreement from the MDRP, effective October 1, 2018, which is the first day of the full calendar quarter that begins at least six months after the effective date of the updated NDRA.

Participating manufacturers in the MDRP must obtain a rebate agreement for each of their labeler codes that market covered outpatient drugs (CODs). If your company has any associated labeler codes that meet the requirements of section 1927 of the Social Security Act and do not have an active NDRA, a new NDRA or reinstatement (if applicable) must be requested and will be subject to the new NDRA or reinstatement process that can be found at https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/national-drug-rebate-agreement/index.html. Requests for a new NDRA or a reinstatement should be sent to drugrebateagreement@cms.hhs.gov.

INSTRUCTIONS FOR COMPLETING THE UPDATED NDRA

Attached to this email is a copy of the updated NDRA and the 367d Labeler Contact Form for your labeler code's review and signature. A downloadable copy of the updated agreement and current 367d form can also be found on the Drug Data Reporting for Medicaid (DDR) system's Bulletin page.

1. Review, sign, and complete page 9 of the updated NDRA, along with your completed 367d Labeler Contact Form. Please note that the signature can be digital or a scanned copy of an ink signature.

2. Return the entire NDRA and 367d form to CMS via email to DrugRebateAgreement@cms.hhs.gov. Do NOT send the original signature through the mail.

3. Once CMS has received your signed NDRA and completed 367d form, we will send you a confirmation email containing an executed copy of the NDRA for your records.

If you have any questions regarding the updated NDRA or requesting a new rebate agreement or reinstatement, please contact us at DrugRebateAgreement@cms.hhs.gov

Thank you,
CMS Drug Rebate Agreement Operations

Department of Health & Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-14-26
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

National Drug Rebate Agreement
Between the Secretary of Health and Human Services
(Hereinafter referred to as "the Secretary") and the Manufacturer

The Secretary, on behalf of the U.S. Department of Health and Human Services and all states which have a Medicaid State Plan approved under 42 U.S.C. 1396a, and the manufacturer, on its own behalf, for purposes of section 1927 of the Social Security Act ("the Act"), 42 U.S.C. 1396r-8, hereby agree to the following:

I. Definitions

The terms defined in this section will, for the purposes of this agreement, have the meanings specified in section 1927 of the Act and implementing Federal regulations, as interpreted and applied herein:

(a) "Average Manufacturer Price (AMP)" will have the meaning set forth in section 1927(k)(1) of the Act as implemented by 42 CFR 447.504.

(b) "Base Consumer Price Index-Urban (CPI-U)" is the CPI-U for September, 1990. For drugs approved by the Food and Drug Administration (FDA) after October 1, 1990, "Base CPI-U" means the CPI-U for the month before the month in which the drug was first marketed.

(c) "Base Date AMP" will have the meaning set forth in sections 1927(c)(2)(A)(ii)(II) and 1927(c)(2)(B) of the Act.

(d) "Best Price" will have the meaning set forth in section 1927(c)(1)(C) of the Act as implemented by 42 CFR 447.505.

(e) "Bundled Sale" will have the meaning set forth in 42 CFR 447.502.

(f) "Centers for Medicare & Medicaid Services (CMS)" means the agency of the U.S. Department of Health and Human Services having the delegated authority to operate the Medicaid Program.

(g) "Consumer Price Index-Urban (CPI-U)" will have the meaning set forth in 42 CFR 447.502.

(h) "Covered Outpatient Drug" will have the meaning set forth in sections 1927(k)(2), (k)(3) and (k)(4) of the Act as implemented by 42 CFR 447.502.

(i) "Depot Price" means the price(s) available to any depot of the federal government, for purchase of drugs from the Manufacturer through the depot system of procurement.

(j) "Innovator Multiple Source Drug" will have the meaning as set forth in section 1927(k)(7)(A)(ii) of the Act as implemented by 42 CFR 447.502.

(k) "Manufacturer" will have the meaning as set forth in section 1927(k)(5) of the Act as implemented by 42 CFR 447.502.

(l) "Marketed" means that a covered outpatient drug is available for sale by a manufacturer in the states.

(m) "Monthly AMP" will have the meaning as set forth in 42 CFR 447.510.

(n) "Multiple Source Drug" will have the meaning as set forth in section 1927(k)(7)(A)(i) of the Act as implemented by 42 CFR 447.502.

(o) "National Drug Code (NDC)" will have the meaning as set forth in 42 CFR 447.502.

(p) "Non-innovator Multiple Source Drug" will have the meaning as set forth in section 1927(k)(7)(A)(iii) of the Act as implemented by 42 CFR 447.502.

(q) "Quarterly AMP" will have the meaning as set forth in 42 CFR 447.504.

(r) "Rebate period" will have the meaning as set forth in section 1927(k)(8) of the Act as implemented by 42 CFR 447.502.

(s) "Secretary" means the Secretary of the U.S. Department of Health and Human Services, or any successor thereto, or any officer or employee of the U.S. Department of Health and Human Services or successor agency to whom the authority to implement this agreement has been delegated. In this agreement, references to CMS indicate such successor authority.

(t) "Single-Award Contract" means a contract between the Federal Government and a Manufacturer resulting in a single supplier for a Covered Outpatient Drug within a class of drugs. The Federal Supply Schedule is not included in this definition as a single award contract.

(u) "Single-Award Contract Price" means a price established under a Single-Award Contract.

(v) "Single Source Drug" will have the meaning set forth in section 1927(k)(7)(A)(iv) of the Act as implemented by 42 CFR 447.502.

(w) "State Drug Utilization Data" means the total number of both fee-for-service (FFS) and managed care organization (MCO) units of each dosage form and strength of the manufacturer's covered outpatient drugs dispensed and/or paid for, as applicable during a rebate period under a Medicaid State Plan, other than units dispensed to Medicaid beneficiaries that were purchased by covered entities through the drug discount program under section 340B of the Public Health Service Act; state utilization data is supplied on the CMS-R-144 form (OMB control number: 0938-0582) (that is, the state rebate invoice).

(x) "States" will have the meaning as set forth in 42 CFR 447.502.

(y) "State Medicaid Agency" means the agency designated by a state under sections 1902(a)(5) and 1927(k)(9) of the Act to administer or supervise the administration of the Medicaid program.

(z) "Unit" means drug unit in the lowest dispensable amount. The manufacturer will specify the unit information associated with each covered outpatient drug per the instructions provided in CMS-367c (OMB control number 0938-0578).

(aa) "Unit Rebate Amount (URA)" means the computed amount to which the state drug utilization data is applied by states in invoicing the manufacturer for the rebate payment due.

(bb) "United States" will have the meaning as set forth in 42 CFR 447.502.

(cc) "Wholesaler" will have the meaning as set forth in section 1927(k)(11) of the Act as implemented by 42 CFR 447.502.

II. Manufacturer's Responsibilities

In order for the Secretary to authorize that a state receive payment for the manufacturer's drugs under Title XIX of the Act, 42 U.S.C. Section 1396 et seq., the manufacturer agrees to the requirements as implemented by 42 CFR 447.510 and the following:

(a) The manufacturer shall identify an individual point of contact for the Legal, Invoice, and Technical contacts at a United States address to facilitate the necessary communications with states with respect to rebate invoice issues.

(b) Beginning with the quarter in which the National Drug Rebate Agreement (rebate agreement) is signed for all covered outpatient drugs of all labeler codes of a manufacturer calculate, and report all required pricing data on every covered outpatient drug by NDC in accordance with section 1927 of the Act and as implemented by 42 CFR 447.510. Furthermore, except as provided under section V.(b). of this agreement, manufacturers are required to calculate a URA and make a rebate payment in accordance with each calculated URA to each State Medicaid Agency for the manufacturer's covered outpatient drug(s) by NDC paid for by the state during a rebate period. CMS may calculate a URA based on manufacturer-submitted product and pricing data and provide the URA to states in order to facilitate rebate billing. However, CMS's URA calculation does not relieve the manufacturer of its responsibility to calculate the URA.

(c) In accordance with the specifications pursuant to Office of Management and Budget (OMB)-approved CMS-367c form, report all covered outpatient drugs and corresponding drug product, pricing, and related data to the Secretary, upon entering into this agreement. This information is to be updated as necessary to include new NDCs and updates to existing NDCs. CMS uses drug information listed with FDA, such as Marketing Category and Drug Type, to be able to verify that an NDC meets the definition of a covered outpatient drug, therefore, manufacturers should ensure that their NDCs are electronically listed with FDA. Reports to CMS should include all applicable NDCs identifying the drug product which may be dispensed to a beneficiary, including package NDCs (outer package NDCs and inner package NDCs).

(d) Beginning with the effective date quarter and in accordance with the specifications pursuant to OMB-approved CMS-367a form (OMB control number 0938-0578), report quarterly pricing data to the Secretary for all covered outpatient drugs in accordance with 42 CFR 447.510. This includes reporting for any package size which may be dispensed to the beneficiary. The manufacturer agrees to provide such information not later than 30 days after the end of each rebate period beginning with the effective date quarter. Adjustments to all prior quarterly pricing data must be reported for a period not to exceed 12 quarters from when the pricing data were originally due as required under 42 CFR 447.510(b).

(e) In accordance with the OMB-approved CMS-367b form (OMB control number 0938-0578), report information including monthly AMPs and monthly AMP units for all covered outpatient drugs in accordance with 42 CFR 447.510. The manufacturer agrees to provide such information not later than 30 days after the end of the month of the effective date, and not later than 30 days after the end of each month thereafter.

(f) Except as provided under V.(b)., to make rebate payments not later than 30 days after receiving the state rebate invoice. The manufacturer is responsible for timely payment of the rebate within 30 days so long as the state invoice contains, at a minimum, the number of units paid by NDC in accordance with 1927(b)(1) of the Act. To the extent that changes in product, pricing, or related data cause increases to previously-submitted total rebate amounts, the manufacturer will be responsible for timely payment of those increases in the same 30-day time frame as the current rebate invoice. To the extent that changes in product, pricing, or related data cause decreases to previously-submitted total rebate amounts, the manufacturer should communicate with the states regarding where to apply the line-item (NDC-level) credit.

(g) To comply with the conditions of 42 U.S.C. section 1396r-8, changes thereto, implementing regulations, agency guidance and this Agreement.

(h) In accordance with 1927(a)(1) of the Act, rebate agreements between the Secretary and the manufacturer entered into before March 1, 1991 are retroactive to January 1, 1991. Rebate agreements entered into on or after March 1, 1991 shall have a mandatory effective date equal to the first day of the rebate period that begins more than 60 days after the date the agreement is entered into. Rebate agreements entered into on or after November 29, 1999 will also have an effective date equal to the date the rebate agreement is entered into that will permit optional state coverage of the manufacturer's NDCs as of that date.

(i) To obtain and maintain access to the system used by the Medicaid Drug Rebate program, use that system to report required data to CMS, and ensure that their contact information is kept updated as required in the OMB-approved CMS-367d form (OMB control number 0938-0578).

(j) To continue to make a rebate payment on all of its covered outpatient drugs for as long as an agreement with the Secretary is in force and state utilization data reports that payment was made for that drug, regardless of whether the manufacturer continues to market that drug. If there are no sales by the manufacturer during a rebate period, the AMP and best price reported in the prior rebate period should be used in calculating rebates.

(k) To keep records (written or electronic) of the data and any other material from which the

calculations of AMP and best price were derived in accordance with 42 CFR 447.510, and make such records available to the Secretary upon request. In the absence of specific guidance in section 1927 of the Act, federal regulations and the terms of this agreement, the manufacturer may make reasonable assumptions in its calculations of AMP and best price, consistent with the purpose of section 1927 of the Act, federal regulations and the terms of this agreement. A record (written or electronic) explaining these assumptions must also be maintained by the manufacturer in accordance with the recordkeeping requirements in 42 CFR 447.510, and such records must be made available to the Secretary upon request.

(l) To notify CMS of any filing of bankruptcy, and to transmit such filing to CMS within seven days of the date of filing.

III. Secretary's Responsibilities

(a) The Secretary will employ best efforts to ensure the State Medicaid Agency shall report to the manufacturer, not later than 60 days after the last day of each rebate period, the rebate invoice (CMS-R-144) or the minimum utilization information as described in section II.(f). of this agreement, that is, information about Medicaid utilization of covered outpatient drugs that were dispensed and/or paid for, as applicable, during the rebate period. Additionally, the Secretary will expect any changes to prior quarterly state drug utilization data to be reported at the same time.

(b) The Secretary may survey those wholesalers and manufacturers that directly distribute their covered outpatient drugs to verify manufacturer prices and may impose civil monetary penalties as set forth in section 1927(b)(3)(B) of the Act and section IV of this agreement.

(c) The Secretary may audit manufacturer information reported under section 1927(b)(3)(A) of the Act.

IV. Penalty Provisions

(a) The Secretary may impose a civil monetary penalty under section III.(b)., as set forth in 1927(b)(3)(B) of the Act and applicable regulations, on a wholesaler, manufacturer, or direct seller of a covered outpatient drug, if a wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request by the Secretary, or the Secretary's designee, for information about covered outpatient drug charges or prices in connection with a survey or knowingly provides false information, including in any of its quarterly reports to the Secretary. The provisions of section 1128A of the Act (other than subsection (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply as set forth in section 1927(b)(3)(B) of the Act and applicable regulations.

(b) The Secretary may impose a civil monetary penalty, for each item of false information as set forth in 1927(b)(3)(C)(ii) of the Act and applicable regulations.

(c) The Secretary may impose a civil monetary penalty for failure to provide timely information on AMP, best price or base date AMP. The amount of the penalty shall be determined as set forth in 1927(b)(3)(C)(i) of the Act and applicable regulations.

(d) Nothing in this Agreement shall be construed to limit the remedies available to the United States government or the states for a violation of this Agreement or any other provision of law.

V. Dispute Resolution

(a) In the event a manufacturer discovers a potential discrepancy with state drug utilization data on the rebate invoice, which the manufacturer and state in good faith are unable to resolve prior to the payment due date, the manufacturer will submit a Reconciliation of State Invoice (ROSI) form, the CMS-304 (OMB control number: 0938-0676), to the state. If such a discrepancy is discovered for a prior rebate period's invoice, the manufacturer will submit a Prior Quarter Adjustment Statement (PQAS) form, CMS-304a (OMB control number: 0938-0676), to the state.

(b) If the manufacturer disputes in good faith any part of the state drug utilization data on the rebate invoice, the manufacturer shall pay the state for the rebate units not in dispute within the required due date in II.(f). Upon resolution of the dispute, the manufacturer will either pay the balance due, if any, plus interest as set forth in section 1903(d)(5) of the Act, or be issued a credit by the state by the due date of the next quarterly payment in II.(f).

(c) The state and the manufacturer will use their best efforts to resolve a dispute arising under (a) or (b) above within a reasonable time frame after the state's receipt of the manufacturer's ROSI/PQAS. In the event that the state and manufacturer are not able to resolve the dispute within a reasonable time frame, CMS will employ best efforts to ensure the state makes available to the manufacturer the same state hearing mechanism available to providers for Medicaid payment disputes (42 CFR 447.253(e)).

(d) Nothing in this section shall preclude the right of the manufacturer to audit the state drug utilization data reported (or required to be reported) by the state. The Secretary encourages the manufacturer and the state to develop mutually beneficial audit procedures.

(e) The state hearing mechanism is not binding on the Secretary for purposes of the Secretary's authority to implement the civil money penalty provisions of the statute or this agreement.

VI. Confidentiality Provisions

(a) Pursuant to section 1927(b)(3)(D) of the Act and this agreement, information disclosed by the manufacturer in connection with this agreement is confidential and, notwithstanding other laws, will not be disclosed by the Secretary or State Medicaid Agency in a form which reveals the manufacturer, or prices charged by the manufacturer, except as authorized under section 1927(b)(3)(D).

(b) The manufacturer will hold state drug utilization data confidential. If the manufacturer audits this information or receives further information on such data, that information shall also be held confidential. Except where otherwise specified in the Act or agreement, the manufacturer will observe confidentiality statutes, regulations, and other properly promulgated policy concerning such data.

(c) Notwithstanding the nonrenewal or termination of this agreement for any reason, these confidentiality provisions will remain in full force and effect.

VII. Nonrenewal and Termination

(a) Unless otherwise terminated by either party pursuant to the terms of this agreement, the agreement shall be effective beginning on the date specified in section II.(h). of this agreement and shall be automatically renewed for additional successive terms of one year from the date specified in section II.(h)., unless the manufacturer gives written notice of intent not to renew the agreement at least 90 days before the end of the current period.

(b) In accordance with section VII.(a). of this agreement and section 1927(b)(4)(B)(ii) of the Act, the manufacturer may terminate the agreement for any reason, and such termination shall become effective the later of the first day of the first rebate period beginning 60 days after the manufacturer gives written notice requesting termination, or CMS initiates termination via written notice to the manufacturer.

The Secretary may terminate the agreement for failure of a manufacturer to make rebate payments to the state(s), failure to report required data, for other violations of this agreement, or other good causes upon 60 days prior written notice to the manufacturer of the existence of such violation or other good causes. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(c) Manufacturers on the Office of Inspector General's (OIG's) List of Excluded Individuals/Entities (Exclusion List) will be subject to immediate termination from the Medicaid drug rebate program unless and until the manufacturer is reinstated by the OIG. Appeals of exclusion and any reinstatement will be handled in accordance with section 1128 of the Act and applicable regulations. Manufacturers that are on the OIG Exclusion List and are reinstated by the OIG under certain circumstances may be evaluated for reinstatement to the Medicaid drug rebate program by CMS. Reinstatement to the Medicaid drug rebate program would be for the next rebate period that begins more than 60 days from the date of the OIG's reinstatement of the manufacturer after exclusion.

(d) If this rebate agreement is terminated, the manufacturer is prohibited from entering into another rebate agreement as set forth in section 1927(b)(4)(C) of the Act for at least one rebate period from the effective date of the termination. The manufacturer must also address to the satisfaction of CMS any outstanding violations from any previous rebate agreement(s), including, but not limited to, payment of any outstanding rebates and also make good faith efforts to appeal or resolve matters pending with the OIG relating to the MDRP or exclusion as referenced in subsection (c) of this section, unless the Secretary finds good cause for earlier reinstatement.

(e) Any nonrenewal or termination will not affect rebates due before the effective date of termination.

VIII. General Provisions

(a) This agreement is authorized by the applicable provisions of sections 1902, 1903, 1905, and 1927 of the Act, and the implementing regulations at 42 CFR Part 447. This agreement is subject to any changes in the Medicaid statute or regulations that affect the rebate program.

(b) Any notice required to be given pursuant to the terms and provisions of this agreement will be permitted in writing or electronically.

Notice to the Secretary will be sent to:

Centers for Medicaid and CHIP Services
Disabled & Elderly Health Programs Group
Division of Pharmacy
Mail Stop S2-14-26
7500 Security Blvd
Baltimore, MD 21244

The CMS address may be updated upon notice to the manufacturer.

Notice to the manufacturer will be sent to the email and/or physical mailing address as provided under section X of this agreement and updated upon manufacturer notification to CMS at the email and/or address in this agreement.

(c) In the event of a transfer in ownership of the manufacturer, this agreement and any outstanding rebate liability are automatically assigned to the new owner subject to the conditions as set forth in section 1927 of the Act.

(d) Nothing in this agreement will 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, this agreement will be construed in all respects as if any invalid or unenforceable provision were eliminated, and without any effect on any other provision.

(e) Nothing in this agreement shall be construed as a waiver or relinquishment of any legal rights of the manufacturer or the Secretary under the Constitution, the Act, other federal laws, or state laws.

(f) The rebate agreement shall be construed in accordance with Federal law and ambiguities shall be interpreted in the manner which best effectuates the statutory construct.

(g) The terms "State Medicaid Agency" and "Manufacturer" incorporate any contractors which fulfill responsibilities pursuant to the agreement unless such contractors are specifically excluded in the rebate agreement or such exclusion is specifically agreed to by an appropriate CMS official.

(h) Except for the conditions specified in II.(g). and VIII.(a)., as well as applicable OMB-approved forms, this agreement will not be altered.

(i) In the event that a due date falls on a weekend or Federal holiday, the report or other item will be due on the first business day following that weekend or Federal holiday.

IX. CMS-367

CMS-367 attached hereto is part of this agreement.

X. Signatures

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By: _____ Date: _____
(signature)

Michael Nardone, Director
Disabled and Elderly Health Programs Group
Center for Medicaid and CHIP Services
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services

ACCEPTED FOR THE MANUFACTURER

I certify that I have made no alterations, amendments or other changes to this rebate agreement.

By: _____ Andrew G. Long
(signature) (please print name)

Title: Chief Financial Officer

Name of Manufacturer: Insys Manufacturing, LLC

Manufacturer Address 1333 S Spectrum Blvd
Suite 100, Chandler, AZ 85286

Manufacturer Labeler Code: _____

Date: 3-29-18

MEDICAID DRUG REBATE AGREEMENT

ENCLOSURE B (PAGE 1 OF 2)
SUPPLEMENTAL DATA SHEET

LABELER CODE (as assigned by FDA)

LABELER NAME (Corporate name associated with labeler code)

LEGAL CONTACT – Person to contact for legal issues concerning the rebate agreement

NAME OF CONTACT

AREA PHONE NUMBER EXTENSION

EMAIL ADDRESS:

NAME OF CORPORATION

STREET ADDRESS

CITY STATE ZIP CODE

INVOICE CONTACT – Person responsible for processing invoice utilization data

NAME OF CONTACT

AREA PHONE NUMBER EXTENSION

EMAIL ADDRESS:

NAME OF CORPORATION

STREET ADDRESS

CITY STATE ZIP CODE

Note: This sheet is to be returned with the signed rebate agreement. If more than one labeler code, attach one sheet for each code.

MEDICAID DRUG REBATE AGREEMENT

ENCLOSURE B (PAGE 2 OF 2)
SUPPLEMENTAL DATA SHEET

LABELER CODE (as assigned by FDA)

LABELER NAME (Corporate name associated with labeler code)

TECHNICAL CONTACT – Person responsible for sending and receiving data

NAME OF CONTACT

AREA PHONE NUMBER EXTENSION

FAX #

EMAIL ADDRESS:

NAME OF CORPORATION

STREET ADDRESS

CITY STATE ZIP CODE

Note: This sheet is to be returned with the signed rebate agreement. If more than one labeler code, attach one sheet for each code.

CMS-367d (Exp. 03/31/2019), OMB No. 0938-0578 According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0578. The time required to complete this information collection is estimated to average 1 hour per response, including the time to review instructions, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

EXHIBIT C

MEDICARE COVERAGE GAP DISCOUNT PROGRAM AGREEMENT

Between

The Secretary of Health and Human Services
(hereinafter referred to as "the Secretary")

and

The Manufacturer Identified in Section X of this Agreement
(hereinafter referred to as "the Manufacturer")

The Secretary, on behalf of the Department of Health and Human Services, and the Manufacturer, on its own behalf, for purposes of sections 1860D-14A and 1860D-43 of the Social Security Act (the Act), as set forth in the Patient Protection and Affordable Care Act of 2010, Pub. L. 111-148, and the Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152, collectively known as the Affordable Care Act, hereby agree to the following:

I. DEFINITIONS

The terms defined in this section will, for the purposes of this Agreement, have the meanings specified in sections 1860D-1 through 1860D-43 of the Act as interpreted and applied herein:

(a) "Applicable Beneficiary" as defined in 42 CFR §423.100 means an individual who on the date of dispensing, as determined at the time of dispensing or thereafter, of a covered Part D drug:

1. Is enrolled in a prescription drug plan or an MA-PD plan;

2. Is NOT enrolled in a qualified retiree prescription drug plan:

3. Is NOT entitled to an income-related subsidy under 1860D-14(a) of the Act;

4. Has reached or exceeded the initial coverage limit under section 1860D-2(b)(3) of the Act during the year; and

5. Has NOT incurred costs for covered Part D drugs in the year equal to the annual out-of-pocket threshold specified in section 1860D-2(b)(4)(B) of the Act. This does not mean that an applicable beneficiary who has already moved through the coverage gap is not eligible for applicable discounts for applicable drugs dispensed while the applicable beneficiary was in the coverage gap.

(b) "Applicable Discount" has the meaning given such term in 42 CFR §423.2305.

(c) "Applicable Drug" has the meaning given such term in 42 CFR §423.100.

(d) "Centers for Medicare & Medicaid Services (CMS)" means the agency of the Department of Health and Human Services having the delegated authority to operate the Medicare program.

(e) "Coverage Gap" has the meaning set forth in 42 CFR §423.100.

(f) "Covered Part D drug" has the meaning as set forth in 42 CFR §423.100.

(g) "Date of Dispensing" means the date of service.

(h) "Discount Program" means the Medicare Coverage Gap Discount Program established under §1860D-14A of the Act.

(i) "Labeler Code" has the meaning set forth in 42 CFR §423.2305.

(j) "Manufacturer" s the meaning given such term in 42 CFR §423.2305.

(k) "Medicare Part D Discount Information" as defined in 42 CFR §423.2305 means information sent from CMS or the TPA to the Manufacturer along with each quarterly invoice that is derived from applicable data elements available on prescription drug events (PDEs) as determined by CMS. This information is set forth in Exhibit A of this Agreement.

(l) "National Drug Code (NDC)" as defined in 42 CFR §423.2305 means the unique identifying prescription drug product number that is listed with the Food and Drug Administration (FDA) identifying the product and package size and type. For the purposes of this Agreement, unless otherwise specified, the NDC refers to the 11-digit (inclusive of 5 digit labeler code, 4 digit product code, and 2 digit package size code) NDC.

(m) "Negotiated Price" has the meaning given such term in 42 CFR §423.2305.

(n) "Part D drug" has the meaning given such term in 42 CFR §423.100.

(o) "Part D plan" has the meaning given such term in section 42 CFR §423.4.

(p) "Part D Sponsor" has the meaning given such term in section 42 CFR §423.4.

(q) "Part D Supplemental benefits" has the meaning given such term in 42 CFR §423.100.

(r) "Prescription Drug Event (PDE)" refers to a summary record that documents the final adjudication of a Part D dispensing event.

(s) "Qualified Retiree Prescription Drug Plan" has the meaning given such term in §1860D-22(a)(2) of the Act.

(t) "Secretary" means the Secretary of the United States Department of Health and Human Services, or any successor thereto, or any officer or employee of the Department of Health and Human Services or successor agency to whom the authority to implement this Agreement has been delegated.

(u) “Third Party Administrator (TPA)” has the meaning given such term in 42 CFR §423.2305.

II. MANUFACTURER'S RESPONSIBILITIES

In order for Part D coverage to be available for applicable drugs of a Manufacturer, the Manufacturer agrees to the following:

(a) All the applicable requirements and conditions set forth in 42 CFR §423 and general instructions.

(b) To reimburse all applicable discounts provided by Part D sponsors on behalf of the Manufacturer for all applicable drugs having NDCs with the Manufacturer's FDA-assigned labeler code(s) invoiced to the Manufacturer within a maximum of three (3) years of the date of dispensing based upon information reported to CMS by Part D sponsors as described in 42 CFR §423.2315(b)(2).

(c) As described in 42 CFR §423.2315(b)(3), to pay each Part D sponsor in the manner specified by CMS within 38 calendar days of receipt invoice and Medicare Part D Discount Information for the applicable discounts included on the invoice, except as specified in 42 CFR §423.2330(c)(3). The invoice will be calculated by CMS (or the TPA) based upon PDE information reported to CMS by such Part D sponsor during the specified quarter, which may include PDEs with dates of service from prior quarters. Receipt of the invoice shall be considered to be one (1) calendar day after the TPA electronically transmits the invoice to the Manufacturer or otherwise notifies the Manufacturer that it is available (e.g., it is posted on a secure web site for download).

(d) To provide CMS with all labeler codes for all the manufacturer's applicable drugs and to promptly update such list with any additional labeler codes for applicable drugs as described in 42 CFR §423.2315(b)(4).

(e) To collect, have available, and maintain appropriate data, including data related to Manufacturer's labeler codes, FDA drug approvals, FDA NDC Directory listings, NDC last lot expiration dates, utilization and pricing information relied on by the Manufacturer to dispute quarterly invoices, and any other data CMS determines are necessary to carry out the Discount Program, for a period of not less than 10 years from the date of payment of the invoice as described in 42 CFR §423.2315(b)(5).

(f) To comply with conditions in sections 1860D-14A and 1860D-43 of the Act as interpreted and applied by this Agreement and any changes to the Medicare statute that affect the Discount Program.

(g) To comply with the requirements imposed by CMS for purposes of administering the Discount Program.

(h) To pay all applicable discounts provided by Part D sponsors on behalf of the Manufacturer for all applicable drugs having NDCs with the Manufacturer's FDA-assigned labeler code(s) for applicable dates of service except for those dates of service after the marketing end date, which is the last lot expiration date, specified in a product's structured product labeling electronically submitted to the FDA, if such marketing end date was submitted to the FDA prior to such date.

(i) To submit to periodic audits of data and documentation referenced in sections II (e) and V (d) of this Agreement and as described in 42 CFR §423.2330. Such notice shall include a description of the scope of the audit and shall be reasonably tailored to the specific purpose of the audit.

(j) To comply with the audit and dispute resolution requirements described in section V of this Agreement and 42 CFR §423.2330 as described in 42 CFR §423.2315(b)(6).

(k) To comply with the confidentiality requirements set forth in section VI of this Agreement.

(l) To electronically list and maintain an up-to-date electronic FDA listings of all NDCs of the Manufacturer, including providing information about discontinued drugs to enable the publication of accurate information regarding what drugs, identified by NDC, are in current distribution as described in 42 CFR §423.2315(b)(7).

(m) To maintain up-to-date NDC listings with the electronic database vendors to which the manufacturer provides NDCs for pharmacy claims processing as described in 42 CFR §423.2315(b)(8).

(n) To enter into and have in effect, under terms and conditions specified by CMS, an agreement with the TPA as described in 42 CFR §423.2315(b)(9).

(o) To pay quarterly invoices directly to accounts established by Part D sponsors via electronic funds transfer, or other manner if specified by CMS, within the time period specified in subsection (c) of this section and within 5 business days of the transfer to provide the TPA with electronic documentation of such payment in a manner specified by CMS as described in 42 CFR §423.2315(b)(10).

(p) To use information disclosed to the Manufacturer on the invoice, as part of the Medicare Part D Discount Information, or upon audit or dispute only for purposes of paying the discount under the Discount Program as described in 42 CFR §423.2315(b)(11).

(q) The Manufacturer's full compliance with the responsibilities listed in this Section II shall constitute satisfaction of the Manufacturer's responsibilities under the Discount Program. Reliance on the information in the invoice shall satisfy any obligation of the Manufacturer to determine the amount of money to pay to any Part D sponsor under this Agreement or Section 1860D-14A or other relevant statutes.

III. SECRETARY'S RESPONSIBILITIES

(a) The Secretary shall require Part D sponsors to make applicable discounts available to applicable beneficiaries at the pharmacy, by mail order service, or at any other point-of-sale for applicable drugs beginning January 1, 2014. The Secretary shall also require Part D sponsors to make applicable discounts available to applicable beneficiaries after the point-of-sale if it is later determined that a drug dispensed to a beneficiary was an applicable drug dispensed to an applicable beneficiary.

(b) The Secretary is responsible for monitoring compliance by the Manufacturer with the terms of this Agreement and with monitoring compliance by Part D sponsors and the TPA with their respective obligations in connection with the Discount Program.

(c) The Secretary is responsible for collecting PDE information from Part D sponsors, for monitoring and tracking the applicable discounts provided by Part D sponsors and reimbursed by Manufacturers for applicable drugs, and for implementing internal control measures designed to ensure the accuracy and appropriateness of discount payments provided by Part D sponsors.

(d) In accordance with section V of this Agreement and as described in 42 CFR §423.2330, the Secretary may audit the Manufacturer periodically with respect to the Manufacturer's labeler codes, NDC last lot expiration dates, utilization and pricing information relied on by the Manufacturer to dispute quarterly invoices, and any other data the Secretary determines are necessary to carry out the Discount Program.

(e) The Secretary shall directly or through a contract with one or more third parties (the TPA):

1. Receive and transmit information, including Medicare Part D Discount Information (as defined in section I (k) of this Agreement), among the Secretary, Manufacturer, Part D sponsors and other individuals or entities the Secretary determines appropriate;

2. Receive, distribute, or facilitate the distribution of funds of the Manufacturer to appropriate individuals or entities;

3. Provide adequate and timely information to the Manufacturer as necessary for the Manufacturer to fulfill its obligations under this Agreement;

4. Calculate the invoice and reconcile any discrepancies with applicable discounts reported by Part D sponsors prior to invoicing Manufacturers;

5. Notify the Manufacturer of invoice errors or retroactive adjustments and make any necessary adjustments to subsequent invoices;

6. Permit manufacturers to conduct periodic audits, directly or through contracts, of the data and information used to determine the applicable discounts for applicable drugs of the Manufacturer under the Discount Program in accordance with section V of this Agreement.

(f) The Secretary shall not disclose any identifying beneficiary information in these reports or otherwise under this Discount Program except as may be required by a court with competent jurisdiction.

(g) The Secretary shall be the sole source of information regarding beneficiary eligibility to receive the applicable discount and the Secretary's determination regarding beneficiary eligibility is not subject to audit or dispute by Manufacturer.

(h) The Secretary shall make public a list of Manufacturers' and their reported labeler codes that are subject to an existing Discount Program Agreement.

(i) The Secretary shall ensure that adjustments are made to invoices as a result of any information obtained relating to errors, including information obtained as a result of the Secretary's audit of a Part D sponsor or the TPA or an audit of data and information made available by the TPA as specified in section V performed by a Manufacturer. In the event a systemic error is discovered, the Secretary shall ensure that either CMS or the TPA identify all invoices affected by the error, notify the Manufacturer and determine the impact of the error on invoiced discounts, and adjust the invoices of the affected Manufacturers (or implement an alternative reimbursement process if determined necessary by the Secretary) to correct any underpayment or overpayment that was requested on prior invoices.

IV. PENALTY PROVISIONS

(a) The Secretary shall impose a civil monetary penalty on a Manufacturer that fails to pay applicable discounts under the Agreement and as described in 42 CFR §423.2340. For purposes of this Agreement, the Manufacturer will have failed to pay applicable discounts if payment has not been transmitted within 38 calendar days of receipt of the applicable invoice for each identified Part D sponsor. The amount for each such failure is the amount the Secretary determines is commensurate with the sum of the amount that the Manufacturer would have paid with respect to such discounts under the Agreement, which will then be used to pay the applicable discounts which the Manufacturer failed to provide, plus an additional 25 percent of the amount the Manufacturer would have paid with respect to such discounts under the agreement.

(b) The provisions of section 1128A of the Act (other than subsections (a) and (b)) shall apply to a civil money penalty in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) of the Act.

V. AUDIT AND DISPUTE RESOLUTION

(a) Both parties shall have the right to conduct periodic audits as specified in this section V of this Agreement and as described in 42 CFR §423.2330, directly or through third parties. Periodic shall mean no more often than annual.

(b) The party requesting the audit shall provide the other party with sixty (60) days notice of the reasonable basis for the audit and a description of the information required for the audit as described in 42 CFR §423.2330. The TPA will determine an audit schedule for Manufacturers based upon available resources.

(c) The Manufacturer shall have the right to audit the data and information (specified in Exhibit B) for a statistically significant sample size of PDEs used to determine the applicable discounts for applicable drugs having NDCs with the Manufacturer's FDA-assigned labeler code(s) under the Discount Program as described in 42 CFR §423.2330(a)(3). The Manufacturer is limited to auditing the data and information made available by the TPA and is not permitted to audit CMS records or the records of Part D sponsors. The TPA will make such data and information available on-site and, with the exception of work papers, such information cannot be removed from the audit site. The auditor is further limited to releasing only an opinion of the results of the audit and cannot release any other information obtained from the audit, including its work papers, to its client, employer or any other party as described in 42 CFR §423.2330(a)(4).

(d) The Secretary, as described in 42 CFR §423.2330(b), shall have the right to audit appropriate data, including data related to Manufacturer's labeler codes, NDC last lot expiration dates, utilization and pricing information relied on by the Manufacturer to dispute quarterly invoices and, any other data the Secretary determines are necessary to carry out the Discount Program.

(e) In the event that a Manufacturer disputes a quarterly invoice, the Medicare Part D Discount Information provided by the TPA with the quarterly invoice, or raises other issues arising under the Agreement, the Manufacturer shall provide written notice of the issue or dispute to the TPA within 60 days of receipt of the information that is the subject of the dispute. Such notice shall be accompanied by supporting evidence that is material, specific, and related to the dispute or issue, as described in 42 CFR §423.2330(c)(1) and (2).

(f) The Manufacturer shall not withhold any invoiced discount payments pending dispute resolution with the sole exception of invoiced amounts for applicable drugs having NDCs not specified as being subject to the Agreement, as described in 42 CFR §423.2330(c)(3). If payment is withheld to dispute that an NDC is subject to the Agreement, the Manufacturer shall notify the TPA and applicable Part D sponsors that payment is being withheld for this reason within 38 calendar days of receipt of the applicable invoice.

(g) Manufacturer disputes and appeals will be conducted in accordance with 42 CFR §423.2330(c)(4-6). The Manufacturer and TPA will use their best efforts to resolve the dispute within 60 calendar days of receipt of such notification. If the Manufacturer receives an unfavorable determination from the TPA or the dispute is not resolved within 60 calendar days, CMS will provide for an independent review and determination by an entity specified by CMS within 90 calendar days of receipt of a request by the Manufacturer for such a review. If the Manufacturer receives an unfavorable determination from the TPA, the Manufacturer must request review within 30 calendar days of the Manufacturer's receipt of the unfavorable determination from the TPA. If the Manufacturer does not receive a determination from the TPA within 60 calendar days, the Manufacturer must request review within 90 calendar days after the TPA's receipt of notice of the dispute. If CMS or the Manufacturer receives an unfavorable determination from independent review entity, CMS or the Manufacturer may request review by the CMS Administrator within 30 calendar days of receipt of notification of such determination. The decision by the CMS Administrator is final and binding.

(h) As described in 42 CFR §423.2330(c)(7), CMS will adjust future invoices (or implement an alternative reimbursement process if determined necessary by the Secretary) if the dispute is resolved in favor of the Manufacturer.

VI. CONFIDENTIALITY PROVISIONS

(a) Any confidential information disclosed by the Manufacturer in connection with this Agreement will not be disclosed by the Secretary in a form that identifies the Manufacturer, except as necessary to carry out provisions of section 1860D-14A of the Act or otherwise required by law. This restriction does not limit the Office of Inspector General's authority to fulfill the Inspector General's responsibilities in accordance with applicable Federal law.

(b) Information disclosed to the Manufacturer pursuant to this Agreement shall only be used for purposes of paying the discount under the Discount Program in accordance with the provisions set forth in section VII of this Agreement. CMS or the TPA will disclose to the Manufacturer only the minimum data necessary for the Manufacturer to fulfill its obligations under this Agreement.

(c) Except where otherwise specified in the Act or Agreement, the Manufacturer will observe applicable State confidentiality statutes, regulations and other applicable confidentiality requirements.

(d) Notwithstanding the nonrenewal or termination of this Agreement for any reason, the confidentiality provisions of this Agreement will remain in full force and effect with respect to information disclosed under this Agreement prior to such nonrenewal or termination.

VII. DATA USE PROVISIONS

The Data Use provisions set forth in Exhibit C of this Agreement govern the use of data CMS provides to the Manufacturer either directly or through the TPA for purposes of the administration of the Discount Program pursuant to sections 1860D-14A and 1860D-43 of the Act.

VIII. NONRENEWAL AND TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of this Agreement, the Agreement shall be effective for an initial period of 24 months from the January 1 that follows its execution by both parties, and shall be automatically renewed for a period of 1 year on January 1 each year thereafter, unless terminated under section VIII.(b) or (d) of this Agreement, as described in 42 CFR §423.2345.

(b) As described in 42 CFR §423.2345(a), the Secretary may terminate this Agreement for a knowing and willful violation of the requirements of the Agreement or other good cause shown in relation to the Manufacturer's participation in the Discount Program. The termination shall not be effective earlier than 30 calendar days after the date of notice to the Manufacturer of such termination. The Secretary shall provide the Manufacturer with an opportunity to cure any ground for termination for cause or to show the Manufacturer is in compliance with Section II within thirty (30) calendar days of the Manufacturer’s receipt of the written termination notice. If the Manufacturer cures the violation, or establishes that it was in compliance within the cure period, the Secretary shall repeal the termination notice by written notice.

(c) As described in 42 CFR §423.2345(a)(4) and (5), the Secretary shall provide, upon request, a Manufacturer a hearing with a hearing officer concerning such termination if requested in writing within 15 calendar days of receiving notice of the termination, and such hearing shall take place prior to the effective date of the termination with sufficient time for such effective date to be repealed if the Secretary determines appropriate. If the Manufacturer or CMS receives an unfavorable decision from the hearing officer, the Manufacturer or CMS may request review by the CMS Administrator. The decision of the CMS Administrator is final and binding.

(d) The Manufacturer may terminate this Agreement for any reason. Any such termination shall be effective as of the day after the end of the calendar year if the termination occurs before January 30 of a calendar year or as of the day after the end of the succeeding calendar year if the termination occurs on or after January 30 of a calendar year, as described in 42 CFR §423.2345(b).

(e) Any termination shall not affect the Manufacturer’s responsibility to reimburse Part D sponsors for applicable discounts for applicable drugs having NDCs with the Manufacturer’s FDA-assigned labeler codes that were incurred under the Agreement before the effective date of its termination, as described in 42 CFR §423.2345(c).

(f) In accordance with 42 CFR §423.2345(d), upon the effective date of the termination of this Agreement, CMS will cease releasing data to the Manufacturer under this Agreement, except as necessary to ensure that the Manufacturer reimburses applicable discounts for previous time periods in which the Agreement was in effect, and will notify the Manufacturer to destroy the data file(s) described in section VII of this Agreement. The provisions of sections IV, VI and VII shall survive termination of this Agreement.

(g) Manufacturer reinstatement will be available only upon payment of any and all outstanding applicable discounts incurred during any previous period of the Agreement. The timing of any such reinstatement will be consistent with the requirements for entering into an Agreement under section 1860D-14A(b)(1)(C) of the Act and 42 CFR §423.2345(e).

IX. GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provisions of this Agreement will be sent in writing.

1. Notice to the Secretary will be sent to:
   Center for Medicare
   Division of Part D Policy
   Mailstop C1-26-16
   7500 Security Boulevard
   Baltimore, MD 21244-1850

2. The CMS address may be updated upon written notice to the Manufacturer.

3. Notices to the Manufacturer will be sent to the address as provided with this Agreement and updated upon Manufacturer notification to CMS at the address in this Agreement.

(b) In the event of a transfer in ownership of the Manufacturer, this Agreement is automatically assigned to the new owner, and all terms and conditions of this Agreement remain in effect.

(c) Nothing in this Agreement will 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 provision were eliminated, and without any effect on any other provision.

(d) Nothing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Secretary under the Constitution, the Act, other Federal laws, or State laws.

(e) This Agreement shall be construed in accordance with Federal law and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme. Any litigation arising from or relating to this Agreement shall be resolved in Federal court.

(f) The terms “Medicare” and “Manufacturer” incorporate any contractors which fulfill responsibilities pursuant to the Agreement unless specifically provided for in this Agreement.

(g) Except for the conditions specified in paragraph (a) of this section, this Agreement once finalized, will not be altered by the parties. However, the Secretary retains the authority to amend the model Agreement after consulting with manufacturers and allowing for comment on such amendments.

(h) Nothing in this Agreement shall be construed as requiring coverage under Part D of a Manufacturer’s product if that product does not otherwise meet the definition of a covered Part D drug under 42 CFR §423.100.

(i) 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 to 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.

(j) This Agreement and the exhibits attached hereto contain the entire agreement of the parties with respect to the subject matter of this Agreement, and supersede all prior negotiations, agreements, and understandings with respect thereto.

X. SIGNATURES

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By: Cynthia Tudor, PhD _____ (please print name)

_____ (signature)

Title: Director, Medicare Drug Benefit and C & D Data Group, Center for Medicare

Date: March 14, 2013 05:42 PM

FOR THE MANUFACTURER

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

B. On behalf of the Manufacturer the undersigned individual hereby attests that he or she is authorized to legally bind the Manufacturer to the terms of this Agreement and agrees to all the terms specified herein.

I certify that I have made no alterations, amendments or other changes to this Medicare Coverage Gap Discount Program Agreement.

By: MICHAEL GURRY _____ (electronic signature)

P#: P1344 _____

Name of Manufacturer: INSYS Therapeutics _____

Date: January 23, 2013 03:58 PM _____

Exhibit A

MEDICARE PART D DISCOUNT INFORMATION DATA ELEMENTS

1. Date of Service

2. Service Provider Identifier Qualifier

3. Service Provider Identifier

4. Prescription/Service Reference Number

5. Product/Service Identifier

6. Quantity Dispensed

7. Days Supply

8. Fill Number

9. Reported Gap Discount

Exhibit B

PDE DATA ELEMENTS AVAILABLE UPON AUDIT ONLY

1. Contract Number

2. Plan Benefit Package Identifier

3. Ingredient Cost Paid

4. Dispensing Fee Paid

5. Total Amount Attributed to Sales Tax

6. Low-Income Cost Sharing Amount

7. Non-covered Plan Paid Amount

8. Vaccine Administration Fee

9. Total Gross Covered Drug Cost Accumulator

10. True Out-of-Pocket Accumulator

Exhibit C

DATA USE PROVISIONS

(a) PURPOSE

CMS agrees to provide the Manufacturer with certain data that reside in the Drug Data Processing System (DDPS), an established CMS Privacy Act System of Records. In exchange, the Manufacturer agrees 1) to ensure the integrity, security, and confidentiality of the data by complying with the terms of this Agreement and applicable law, including the Privacy Act and the Health Insurance Portability Accountability Act; and 2) to use the prescription or claim-level data only for purposes of evaluating the accuracy of claimed discounts and resolving disputes concerning the Manufacturer's payment obligations under the Discount Program as described in the applicable statutes, regulations, and this Agreement.

The following provisions address the conditions under which CMS will disclose and the Manufacturer will obtain and use the CMS data file(s) specified in subsection (b)(1) of this section and/or any derivative file(s) that can be used in concert with other information to identify individuals. These provisions supplement any and all agreements between the parties with respect to the use of data from the files specified in subsection (b)(1).

(b) MANUFACTURER'S RESPONSIBILITIES CONCERNING AND LIMITATIONS ON USE OF DISCOUNT INFORMATION

1. The CMS data file(s) covered under this Agreement shall be referred to as "Medicare Part D Discount Information" as defined in section I (k) of this Agreement and shall also include any data provided by CMS or the TPA to the Manufacturer in support of the resolution of payment disputes and audits pursuant to section V of this Agreement (hereinafter referred to as "Discount Information").

2. The Manufacturer agrees to limit the use of the Discount Information to those uses necessary to evaluate the accuracy of claimed discounts and resolve disputes concerning the Manufacturer's payment obligations under the Discount Program. The Manufacturer may not use the Discount Information to perform any functions not governed by this Agreement, including but not limited to non-Coverage Gap Discount payments to Part D sponsors and their subcontractors, payments to other providers of health and drug benefits under any Federal health care program and marketing activities. These restrictions do not apply to the use of aggregated, summary-level data (i.e. not prescription or claim-level data) for financial statement forecasting and accounting purposes.

3. The parties mutually agree that CMS retains all ownership rights to the data file(s) referred to in this Agreement, and that the Manufacturer does not obtain any right, title, or interest in any of the data furnished by CMS.

4. The Manufacturer agrees not to disclose, use or reuse the data covered by this Agreement, including data derived from data covered by this Agreement, except as specified in this Agreement or except as CMS shall authorize in guidance it issues in writing related to the administration of the Discount Program or as otherwise required by law. The Manufacturer further agrees not to, sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement, with the exception that the Manufacturer may grant access to such data to contracted third parties for purposes of assisting the Manufacturer in evaluating the accuracy of claimed discounts, resolving disputes, and otherwise exercising its rights and responsibilities under the Agreement so long as such contracted third parties are subject to the same confidentiality requirements set forth in this Agreement and that the Manufacturer maintains responsibility for ensuring compliance by these third parties with the confidentiality requirements of this Agreement.

5. The Manufacturer agrees that, within the Manufacturer's organization and the organizations of its agents, access to the data covered by the Agreement shall be limited to the minimum amount of data necessary and minimum number of individuals who need access to the data for permitted activities such as those described under paragraphs 2 and 4 above. (i.e., individual's access to the data will be on a need-to-know basis).

6. The parties mutually agree that the aforesaid files(s) (and/or any derivative file(s)), including those files that directly identify proprietary or confidential information of a Part D sponsor or its subcontractors or affiliates and those files that can be used in concert with other information to identify individuals), may be retained by the Manufacturer for a period of ten (10) years from the date of payment of the invoice, hereinafter known as the "Retention Period." The Manufacturer agrees to maintain, and provide upon request to CMS, written documentation of the regular destruction of the files within the required timeframe. The Manufacturer may retain the data beyond the ten year timeframe if the data is the subject of an unresolved audit, government investigation, or litigation, or if required by another applicable law and the Manufacturer notifies the Secretary of such matter and promptly destroys the data once the pending matter is resolved.

7. The Manufacturer agrees to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use or access to it. Further, the Manufacturer (or a contracted third party) agrees that the data must not be physically moved, transmitted or disclosed in any way from or by any site(s) owned, operated, or otherwise controlled by the Manufacturer (or the contracted third party) to any sites outside of the control of the Manufacturer (or the contracted third party) without written approval from CMS unless such movement, transmission or disclosure is required by a law.

8. The Manufacturer agrees to grant access at its facilities to the data to authorized representatives of CMS or DHHS Office of the Inspector General for the purpose of inspecting to confirm compliance with the terms of this Agreement upon reasonable notice and during normal business hours.

9. The Manufacturer agrees that it shall not attempt to link records included in the file(s) specified in subsection (b) 1 to any individually identifiable source of information. This includes attempts to link the data to other CMS data file(s) except that Manufacturers may link to Discount Program data from prior quarters in order to validate that a claim has not been duplicated or that retroactive adjustments have been made. CMS may establish through guidance issued separately to the Manufacturer exceptions to this prohibition that may be necessary for purposes of the administration of the Discount Program.

10. In the event that a Manufacturer inadvertently receives individually identifiable information, the Manufacturer will report the incident to the CMS Action Desk by telephone at (410) 786-2580 or by e-mail notification at cms_it_service_desk@cms.hhs.gov within one hour of the Manufacturer's discovery of the incident. The Manufacturer agrees not to disclose, use or reuse such data or information and acknowledges that the use of unsecured telecommunications, including the Internet, to transmit individually identifiable or deducible information derived from the file(s) specified in subsection (b)(1) is prohibited.

11. The Manufacturer agrees that in the event CMS determines or has a reasonable belief that the Manufacturer has made or may have made a use, reuse or disclosure of the aforesaid file(s) that is not authorized by this Agreement, CMS, at its sole discretion, may require the Manufacturer to: (a) promptly investigate and report to CMS the Manufacturer's determinations regarding any alleged or actual unauthorized use, reuse or disclosure, (b) promptly resolve any problems identified by the investigation; (c) if requested by CMS, submit a formal response to an allegation of unauthorized use, reuse or disclosure; (d) if requested by CMS, submit a corrective action plan with steps designed to prevent any future unauthorized uses, reuses or disclosures; and (e) if requested by CMS, return data files to CMS or destroy the data files it received from CMS under this agreement. The Manufacturer understands that as a result of CMS's determination or reasonable belief that unauthorized uses, reuses or disclosures have taken place, CMS may refuse to release further CMS data to the Manufacturer for a period of time to be determined by CMS.

12. The Manufacturer agrees to report any breach of any information from the CMS data file(s), loss of these data or disclosure to any unauthorized persons to the CMS Action Desk by telephone at (410) 786-2580 or by e-mail notification at cms_it_service_desk@cms.hhs.gov within one hour of the Manufacturer's discovery of the incident and to cooperate fully in the federal security incident process. While CMS retains all ownership rights to the data file(s), as outlined above, the Manufacturer shall bear the cost and liability for any breaches of the data file(s) while they are entrusted to the Manufacturer.

13. The Manufacturer hereby acknowledges that criminal penalties under §1106(a) of the Social Security Act (42 U.S.C. §1306(a)), including a fine not exceeding $10,000 or imprisonment not exceeding 5 years, or both, may apply to disclosures of information that are covered by §1106 and that are not authorized by regulation or by Federal law. The Manufacturer further acknowledges that criminal penalties under the Privacy Act (5 U.S.C. §552a(i)(3)) may apply if it is determined that the any individual employed or affiliated with the Manufacturer knowingly and willfully obtained the file(s) under false pretenses. Any person found to have violated sec. (i)(3) of the Privacy Act shall be guilty of a misdemeanor and fined not more than $5,000. Finally, the Manufacturer acknowledges that criminal penalties may be imposed under 18 U.S.C. §641 if it is determined that the Manufacturer, or any individual employed or affiliated therewith, has taken or converted to his own use data file(s), or received the file(s) knowing that they were stolen or converted. Under such circumstances, they shall be fined under Title 18 or imprisoned not more than 10 years, or both; but if the value of such property does not exceed the sum of $1,000, they shall be fined under Title 18 or imprisoned not more than 1 year, or both.

IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE

In re:	:	
	:	Chapter 11
	:	
INSYS THERAPEUTICS, INC., *et al*.,	:	
	:	Case No. 19-11292 (KG)
	:	
Debtors.	:	
	:	

AFFIDAVIT OF SERVICE

The undersigned hereby certifies that I caused a copy of the Objection of the United States to Notice of Cure Costs and Potential Assumption and Assignment of Executory Contracts and Unexpired Leases in Connection with the Sale to be served by 4:00 p.m. on August 9, 2019, upon those parties who have signed up for the Court's electronic noticing system (CM/ECF) and by electronic mail on the parties included on the attached service list.

Dated: August 9, 2019

Respectfully submitted,

JOSEPH H. HUNT
Assistant Attorney General

DAVID C. WEISS
United States Attorney

ELLEN W. SLIGHTS
Assistant United States Attorney
1007 Orange Street, Suite 700
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/s/ Mary A. Schmergel
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