

Join APC's comprehensive compounding dispensing data reporting initiative

The Alliance for Pharmacy Compounding is launching a groundbreaking project to collect, analyze, and report real-world data on compounded drug dispensing in the United States.

Our goal is simple: give the compounding profession the accurate, credible, statistically valid data it needs to inform policymakers, respond to regulatory challenges, and demonstrate the value and scope of pharmacy compounding.

For years, there's been no reliable way to measure how much compounding is happening nationwide, what types of compounded therapies are being dispensed, or where they're reaching patients. That gap became especially clear during recent shortages of semaglutide and tirzepatide injections.

By joining this project, your compounding pharmacy will help build the first-ever system capable of producing national-level insights on compounding trends.

OUR RESEARCH PARTNER

APC has engaged tenured professors Dr. Hui Shao and Dr. Donghai Liang at the Rollins School of Public Health, Emory University, to oversee our research methodology. Their expertise ensures the process is statistically sound and the results credible.

YOUR DATA IS SECURE

We understand the sensitivity of your dispensing data. That's why:

- Data sharing agreements—included in this packet—clearly spell out your rights and our responsibilities.
- All data will be de-identified before it leaves your pharmacy.
- Researchers will only see aggregated results—never your individual pharmacy's data.
- Data will be stored securely and used only for this project.
- APC will never monetize your data—it's yours, not ours.



Your trust is critical. APC is committed to absolute confidentiality. We will never reveal the identity of participating pharmacies.

WHAT WE'RE ASKING FROM YOU

Participating pharmacies will provide a simple spreadsheet (CSV) with a few key, de-identified data points:

- | | | |
|------------------------------------|-------------------------|------------------|
| • Drug name (and NDC if available) | • Patient date of birth | • Date dispensed |
| • Strength and dosage form | • Patient ZIP code | • Species |

We're not asking for any pricing data at all. Only the fields above. We'll begin with a one-time "baseline" file from recent history, then collect updates at least quarterly to monitor trends. *(Most major dispensing software can generate this report easily, by the way.)*

WHY PARTICIPATE

As you read this, drugmakers are lobbying Congress to mandate reporting of all compounding dispensing to FDA. The question is, who do you trust more to leverage compounding dispensing data accurately: FDA or your industry trade association? Time is of the essence – we want to head off wrong-headed efforts is Congress to mandate reporting – so PLEASE join this project.

By sharing your data, you will:

- Position APC as the credible source for reliable compounding data.
- Strengthen advocacy with hard numbers regulators and legislators can't ignore.
- Spot industry trends before they impact your business.
- Demonstrate compounding's value to healthcare—with facts, not anecdotes.
- Provide FDA with data that can inform decisions about the Drug Shortage List.



Together, we can build the knowledge base our profession needs to protect patient access and shape the future of compounding.

Next step: Review and sign the enclosed Data Sharing Agreement, then return it to APC.





Alliance for
Pharmacy
Compounding

Compounding the Joy of Living

Pharmacy name:

Point of contact:

Pharmacy address:

Contact email:

1. Is your pharmacy compounding only or hybrid?

- ☐ Compounding only
☐ Hybrid

2. Check all that apply:

- ☐ Nonsterile nonhazardous
☐ Nonsterile hazardous
☐ Sterile nonhazardous
☐ Sterile hazardous

3. Do you specialize in veterinary compounding?

- ☐ Yes
☐ No

4. Number of pharmacists:

5. Number of total employees:

Please include a single number in digits only – no ranges or letters/words

6. PCAB or other accreditation?

- ☐ PCAB ☐ Other:
☐ No

6. Do you now or have you in the past 12 months dispensed a compounded medication sourced from a 503B?

- ☐ Yes
☐ No

7. In how many states is your pharmacy currently licensed?

Please include a single number in digits only – no ranges or letters/words

Please return completed data use agreements and contact forms to Missy Wigley at info@a4pc.org.

DATA USE AGREEMENT

This Data Use Agreement (“Agreement”) is entered into this _____ day of _____, 2025 (the “Effective Date”), by _____ and _____ between _____ (“Pharmacy”) and the **Alliance for Pharmacy Compounding (“APC”)**, a nonprofit corporation incorporated in Texas. Each may be referred to as a “Party” and together as the “Parties.”

1. PURPOSE

Pursuant to 45 CFR § 164.514(e)(4), this Agreement governs the terms under which Pharmacy will provide APC with limited dispensing data as part of APC’s national Compounding Data Collection Initiative (“Initiative”). The Initiative’s purpose is to aggregate dispensing data from compounding pharmacies across the United States to generate research, reports, and policy insights. Aggregated findings derived from this data may be shared by APC publicly with policymakers, regulators, media, and other stakeholders to inform education, advocacy, and industry dialogue. The data will not be used for commercial or competitive purposes or to evaluate individual pharmacies.

2. DEFINITIONS

“**Limited Data Set**” means dispensing data that includes only (1) the drug name and NDC (where applicable); (2) the strength and dosage form of the drug; (3) the date the drug was dispensed; (4) the patient’s date of birth; (5) the patient’s gender; (6) the patient’s zip code; and (7) the patient’s species (if an animal). As set forth in 45 CFR § 164.514(e), the term “Limited Data Set” expressly excludes the following Direct Identifiers of the patient or of relatives, employers, or household members of the patient, which shall not be provided to APC:

- (i) Names;
- (ii) Postal address information, other than town or city, State, and zip code;
- (iii) Telephone numbers;
- (iv) Fax numbers;
- (v) Electronic mail addresses;
- (vi) Social security numbers;
- (vii) Medical record numbers;
- (viii) Health plan beneficiary numbers;
- (ix) Account numbers;
- (x) Certificate/license numbers;
- (xi) Vehicle identifiers and serial numbers, including license plate numbers;
- (xii) Device identifiers and serial numbers;
- (xiii) Web Universal Resource Locators (URLs);
- (xiv) Internet Protocol (IP) address numbers;

- (xv) Biometric identifiers, including finger and voice prints; and
- (xvi) Full face photographic images and any comparable images.

“Aggregated Data” means data derived from multiple pharmacy submissions that has been compiled and analyzed in a manner that does not permit the identification of any individual patient or participating pharmacy.

“Business Associate Agreement” means the Business Associate Agreement attached as **Exhibit A** hereto.

“Direct Identifier” means any information that could directly identify an individual or pharmacy, specifically including the information expressly excluded from the definition of Limited Data Set.

“Research Consultants” means the research consultants who will advise APC and its Researcher as to the methodologies of aggregating and analyzing the dispensing data pursuant to the Initiative.

“Researcher” means a Masters of Public Health (MPH) graduate student at Emory University hired by APC through Emory’s Rollins Earn and Learn (REAL) program for the purpose of aggregating and analyzing pharmacy dispensing data pursuant to the Initiative.

3. SCOPE OF DATA COLLECTION

(a) Initial Transfer: Pharmacy shall submit an initial one-time transfer of the Limited Data Set for all compounded prescriptions dispensed during the past 42 months.

(b) Ongoing Transfers: Pharmacy shall thereafter submit the Limited Data Set on a semiannual basis covering each six-month period, on the 15th of January and on the 15th of July.

(c) Data Fields: Each submission shall include **only** the following Limited Data Set:

- Drug Name and NDC (where applicable)
- Strength and Dosage Form
- Date Dispensed
- Patient’s Date of Birth
- Patient’s Gender
- Patient’s ZIP Code
- Patient’s species (if an animal)

Data shall be provided in Excel or CSV format via secure transmission methods.

(d) De-Identification Standards: Pharmacy represents and warrants that the submitted data will only contain the Data Fields set forth above and that no Direct Identifiers will be included with the data submissions.

(e) Compliance with State Law: Pharmacy represents and warrants that its data submissions under this Agreement comply with all applicable federal, state, and local laws and regulations, including but not limited to any state-specific data privacy or health information requirements. Pharmacy acknowledges that APC is relying on Pharmacy's compliance with such laws in accepting and using the submitted data.

4. USE AND DISCLOSURE OF DATA

APC agrees to:

1. Strictly comply with all HIPAA Privacy Rules and the terms of the Business Associate Agreement set forth in **Exhibit A** hereto.
2. Apply a masked code to all data submitted by the pharmacy prior to aggregating Pharmacy's data with the data submitted by other pharmacies;
3. Use the data exclusively to develop aggregated, non-identifiable insights for research, reporting, education, and advocacy purposes, including public-facing communications and external engagement with regulators, policymakers, the media, and industry stakeholders;
4. Not use or disclose the data for commercial purposes including but not limited to data licensing, resale, revenue-generating analytics, or use in any for-profit offering or competitive benchmarking;
5. Not attempt to re-identify or contact any individual;
6. Not disclose Pharmacy identity;
7. Share data only in aggregated form, except with Researcher or Research Consultants under a separate, written Data Use Agreements containing equivalent protections and use restrictions, for the limited purpose of aggregating and analyzing the data;
8. Retain data only as long as reasonably necessary for the purposes described herein;
9. Permit only authorized personnel to access the data on a need-to-know basis;
10. Ensure that no public-facing reports derived from the data disclose information in a manner that could reasonably permit identification of any individual, pharmacy, patient, or small population subgroup.

5. DATA OWNERSHIP AND CONFIDENTIALITY

(a) Ownership: Pharmacy retains all ownership rights in its submitted data. Nothing in this Agreement transfers any ownership or intellectual property rights of the raw data from Pharmacy to APC, Researcher, or Research Consultants.

(b) License: Pharmacy hereby grants to APC, Researcher, and Research Consultants a limited, non-exclusive license to access and use the data solely for statistical analysis and research purposes in accordance with the Initiative.

(d) Confidentiality Obligations: APC shall treat all raw data provided by Pharmacy as confidential and shall implement and maintain commercially reasonable administrative, technical, and physical safeguards to protect such data from unauthorized access, use, or disclosure. These safeguards shall be no less protective than those APC applies to its own confidential and proprietary information of a similar nature. APC shall limit access to the data to only those employees, contractors, or agents who have a legitimate need to know and who are subject to obligations of confidentiality and restricted use consistent with this Agreement.

(e) Confidentiality of Pharmacy-Specific and Provider-Specific Data: APC shall not disclose the identity of Pharmacy's individual-, pharmacy-, or identifiable provider-specific data in any publication, report, or dataset. No reports, publications, or external disclosures shall identify the Pharmacy. APC shall apply aggregation thresholds (e.g., minimum provider count per ZIP code) to prevent indirect identification.

(f) Data Summary: Pharmacy may request a summary of how its data was used or included in aggregated results. Before publishing any report or analysis incorporating Pharmacy data, APC shall provide a draft to Pharmacy upon request for nonbinding review and confirmation of de-identification.

(g) Required Disclosures: Pharmacy acknowledges that APC may be required to use or disclose the protected health information provided to it by Pharmacy as may be required by law, including but not limited to court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.

6. DATA SECURITY

APC shall implement and maintain reasonable administrative, physical, and technical safeguards to protect the confidentiality, integrity, and availability of all data received under this Agreement. Such safeguards shall include, at a minimum:

1. Encryption of data during transmission and while at rest using commercially reasonable standards (e.g., SSL/TLS for transmission; encryption at rest on secured servers);

2. Access controls to ensure that only authorized APC personnel have access to the data, including the use of strong passwords and role-based permissions;
3. Authentication protocols, such as password complexity standards or multi-factor authentication for systems housing or processing the data;
4. Logging and audit capabilities sufficient to monitor access to the data and detect unauthorized activity;
5. Timely destruction or secure deletion of raw data when no longer reasonably needed for the Initiative, unless otherwise required by law or agreed in writing;
6. U.S.-based storage of all data, including any third-party hosted services used for processing or analysis.

APC shall review and update its security practices periodically in light of changes in technology, data sensitivity, and applicable laws. In the event of a suspected or confirmed data breach, APC shall notify the Pharmacy in writing **within 24 hours** and cooperate fully in any response or remediation efforts.

7. TERM AND TERMINATION

This Agreement shall remain in effect until terminated by either Party with sixty (60) days' written notice.

8. LIABILITY AND INDEMNITY

(a) THE DATA IS PROVIDED "AS IS." ALTHOUGH PHARMACY SHALL ENDEAVOR TO PROVIDE ACCURATE AND COMPLETE DATA, PHARMACY MAKES NO REPRESENTATIONS OR WARRANTIES REGARDING ACCURACY OR COMPLETENESS.

(b) Indemnification: APC shall indemnify, defend, and hold harmless Pharmacy and its officers, directors, employees, and agents from and against any and all third-party claims, demands, liabilities, damages, losses, costs, and expenses (including reasonable attorneys' fees) arising out of or related to (i) APC's material breach of this Agreement; (ii) any unauthorized use or disclosure of data by APC or its agents in violation of this Agreement; or (iii) APC's failure to comply with applicable laws, rules, or regulations in connection with its handling of the data. In the event of any unauthorized acquisition, access, or disclosure of Pharmacy's data, APC shall provide written notice to Pharmacy **within 24 hours**, investigate the incident in good faith, and cooperate in any required mitigation or reporting efforts.

(c) Limitation of Liability: To the maximum extent permitted by applicable law, neither Party shall be liable to the other for any indirect, incidental, consequential, special, exemplary, or punitive damages (including, without limitation, lost profits, loss of data, loss of goodwill, or business interruption), arising out of or relating to this Agreement, regardless of the form of action, whether in contract, tort (including negligence), strict

liability, or otherwise, even if such Party has been advised of the possibility of such damages.

9. MISCELLANEOUS

(a) Entire Agreement: This Agreement, including any exhibits, schedules, and addenda attached hereto, constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof, and supersedes all prior and contemporaneous oral or written agreements, representations, and understandings of the Parties. No extrinsic evidence may be used to interpret, modify, or supplement the express terms of this Agreement.

(b) Amendments and Waivers: No amendment, modification, or waiver of any provision of this Agreement shall be effective unless set forth in a written instrument signed by duly authorized representatives of both Parties. No failure or delay by either Party in exercising any right, power, or remedy under this Agreement shall operate as a waiver thereof.

(c) Governing Law; Jurisdiction: This Agreement shall be governed by and construed in accordance with the laws of the **State of Texas**, without regard to its conflict-of-law principles. Each Party irrevocably consents to the exclusive jurisdiction of the state and federal courts located within the **State of Texas** for the resolution of any disputes arising out of or relating to this Agreement.

(d) Independent Contractors: The Parties are independent contractors, and nothing contained in this Agreement shall be construed to create a joint venture, partnership, fiduciary, employment, or agency relationship between the Parties. Neither Party shall have the authority to bind the other Party in any respect.

(e) Assignment: Neither Party may assign or transfer this Agreement or any of its rights or obligations hereunder without the prior written consent of the other Party, except that APC may assign this Agreement without consent in connection with a merger, reorganization, or sale of substantially all of its assets.

(f) Severability: If any provision of this Agreement is held to be illegal, invalid, or unenforceable under any applicable law, such provision shall be severed, and the remaining provisions shall remain in full force and effect.

(g) Force Majeure: Neither Party shall be liable for any failure or delay in performing its obligations under this Agreement (other than payment obligations) due to circumstances beyond its reasonable control, including acts of God, labor disputes, pandemics, governmental actions, war, or natural disasters.

(h) Survival: The provisions of this Agreement that by their nature should survive termination, including but not limited to Section 4 (Use and Disclosure of Data), Section 5 (Data Ownership and Confidentiality), Section 6 (Data Security), Section 8 (Liability and

Indemnity), and this Section 9 (Miscellaneous), shall survive any expiration or termination of this Agreement.

(i) Designated Contact: APC and Pharmacy designate a primary point of contact or compliance officer to receive notifications and respond to inquiries under this Agreement. The contact information for each party is as follows:

Designated Contact for APC:

Name: Scott Brunner
Title: Chief Executive Officer
Email: scott@a4pc.org
Phone: 281-933-8400

Designated Contact for Pharmacy:

Name: _____
Title: _____
Email: _____
Phone: _____

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

By:

Name:
Title:
Date:

ALLIANCE FOR PHARMACY COMPOUNDING

By:

Name: Scott Brunner
Title: Chief Executive Officer
Date:

EXHIBIT A
BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (“Agreement”) is entered into this ____ day of _____, 2025 (the “Effective Date”), by and between _____ (“Covered Entity”) and the **Alliance for Pharmacy Compounding** (“APC” or “Business Associate”) (each a “Party” and collectively the “Parties”).

RECITALS

WHEREAS, the Parties have entered into a **Data Use Agreement** in furtherance of APC’s national Compounding Data Collection Initiative (the “Underlying Contract”).

WHEREAS, the Underlying Contract may cause Business Associate to be provided with, to have access to, and/or to create Protected Health Information (as defined in 45 C.F.R. § 160.103) (“PHI”) on behalf of APC that is subject to the federal privacy regulations (the “Privacy Rule”) and the federal security regulations (the “Security Rule”) issued pursuant to the Health Insurance Portability and Accountability Act (“HIPAA”) and codified at 45 C.F.R. parts 160 and 164, and the Health Information Technology for Economic and Clinical Health Act and any rules promulgated thereunder (“HITECH Act”) as may be amended from time to time.

WHEREAS, the Parties desire to meet their obligations under the Privacy Rule, Security Rule, HIPAA and HITECH Act.

WHEREAS, the Parties desire to make procedural arrangements to ensure that their business relationship meets these regulatory requirements as of the required compliance date(s).

WHEREAS, the Parties desire to set forth the terms and conditions pursuant to which Protected Health Information that is provided by, or created or received by, the Business Associate on behalf of Covered Entity, will be handled between themselves and third Parties.

WHEREAS, the Parties desire to set forth the terms and conditions pursuant to which any Breach of Unsecured Protected Health Information is reported.

WHEREAS, any provisions in any Underlying Contract regarding the limitation or exclusion of liability or damages shall not apply to Business Associate’s breach of its obligations hereunder with respect to PHI.

NOW THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. DEFINITIONS.

1.1 Unless otherwise defined in this Agreement, all capitalized terms used in this Agreement have the meanings ascribed to them in the Privacy Rule, the Security Rule, HIPAA, and the HITECH Act.

1.2 “Breach” shall mean the unauthorized acquisition, access, use, or disclosure of PHI which compromises the security or privacy of such information, except where an unauthorized person to whom such information is disclosed would not reasonably have been able to retain such information.

1.3 “Electronic PHI” shall mean Electronic Protected Health Information, as defined in 45 C.F.R. § 160.103, limited to the information received from or created or received by Business Associate on behalf of Covered Entity.

1.4 “PHI” shall mean Protected Health Information, as defined in 45 C.F.R. § 160.103, limited to the information received from or created or received by Business Associate on behalf of Covered Entity.

1.5 “Required by Law” shall include, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or trial inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.

1.6 “Secretary” shall mean the Secretary of Health and Human Services or his or her designee.

1.7 “Unsecured PHI” shall mean Electronic PHI or PHI that is not secured through the use of a technology or methodology specified by the Secretary in guidance.

2. OBLIGATIONS OF THE PARTIES WITH RESPECT TO PHI.

2.1 Obligations of Business Associate. Business Associate agrees to:

2.1.1 Not use or disclose the PHI other than as permitted or required by this Agreement or other arrangement pursuant to 45 C.F.R. 164.504(e) or as Required by Law. The Business Associate may not use or disclose PHI in a manner that would violate the requirements of 45 C.F.R. 164, if done by the covered entity, except for the purposes specified under 45 C.F.R. 164 (e)(2)(i)(A) or (B) if such uses or disclosures are permitted by this Agreement or other arrangement.

2.1.2 Access only the PHI of patients who are assigned by Covered Entity to Business Associate.

2.1.3 Use appropriate safeguards and comply, where applicable, with subpart C of this part with respect to Electronic PHI, to prevent use or disclosure of PHI other than as provided for by this Agreement.

2.1.4 Comply with the applicable requirements of 45 C.F.R. 164.

2.1.5 Make its policies and procedures, and documentation required by the Security Rule relating to such safeguards, available to the Secretary of the Department of Health and Human Services ("HHS") for purposes of determining Covered Entity's compliance with the Security Rule.

2.1.6 Mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate in violation of the requirements of this Agreement.

2.1.7 Report to Covered Entity any use or disclosure of PHI not provided for by this Agreement of which Business Associate becomes aware, including breaches of unsecured PHI as required by 45 C.F.R. 164.410.

2.1.8 Report to Covered Entity any Security Incident with respect to Electronic PHI of which it becomes aware, including breaches of unsecured PHI as required by 45 C.F.R. 164.410.

2.1.9 Report to Covered Entity any Breach with respect to Electronic PHI of which it becomes aware or which Business Associate should be aware. Such report shall include the identity of each individual whose Unsecured PHI has been, or is reasonably believed to have been, accessed, acquired, or disclosed during such Breach, the circumstance surrounding the Breach, and actions taken by the Business Associate to remediate the Breach.

2.1.10 Ensure that all of its subcontractors and agents that receive, use or have access to PHI agree, in writing, to essentially the same restrictions and conditions on the use and/or disclosure of PHI that apply through this Agreement to Business Associate with respect to such information.

2.1.11 Ensure that any subcontractors that create, receive, maintain, or transmit Electronic PHI on behalf of the Business Associate agree to essentially the same restrictions and conditions that apply to the Business Associate with respect to such information, and agree to comply with the applicable requirements of 45 C.F.R. §164.314 by entering into a contract or other agreement that complies with that section.

2.1.12 At the request of Covered Entity and in the time and manner specified by Covered Entity, provide access to PHI in a Designated Record Set to Covered Entity

or, as directed by Covered Entity, to an Individual in order to meet applicable access requirements of the Privacy Rule.

2.1.13 At the request of Covered Entity and in the time and manner specified by Covered Entity, make amendment(s) to PHI in a Designated Record Set.

2.1.14 Make its internal practices, books and records relating to the use and disclosure of PHI available to the Secretary of HHS, in the time and manner specified by the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule.

2.1.15 Document such disclosures of PHI and information related to such disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with the requirements of the Privacy Rule.

2.1.16 Provide to Covered Entity, in the time and manner specified by Covered Entity, information collected in accordance with Section 2.1.14. of this Agreement, to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI.

2.1.17 Return to Covered Entity or destroy, within thirty (30) days of the termination of this Agreement or any Underlying Contract, all PHI obtained from Covered Entity or created or obtained by Business Associate on behalf of Covered Entity with respect to the affected Underlying Contract(s), including such PHI that is in the possession of Business Associate's subcontractors and agents, and retain no copies if it is feasible to do so, unless otherwise Required by Law. If return or destruction of the PHI is infeasible, Business Associate shall notify Covered Entity of the conditions that make return or destruction infeasible, extend all protections contained in this Agreement to any retained PHI, and limit any further uses and/or disclosures of the PHI to the purposes that make the return or destruction of the PHI infeasible. This Section 2.1.17. shall survive any termination or expiration of this Agreement.

2.1.18 To the extent the Business Associate is to carry out a covered entity's obligation under 45 C.F.R. §164.500, comply with the requirements of this subpart that apply to the covered entity in the performance of such obligation.

2.2 Permitted Uses and Disclosures of PHI by Business Associate. Except as otherwise specified in this Agreement, Business Associate may use and disclose the PHI as reasonably necessary to perform its obligations under the Underlying Contracts. Unless otherwise limited herein, Business Associate may (a) use the PHI in its possession for its proper management and administration and to carry out the legal responsibilities of Business Associate; (b) disclose the PHI in its possession to a third party for the purpose of Business Associate's proper management and administration or to carry out the legal responsibilities of Business Associate, provided that the disclosures are Required By Law or Business Associate obtains reasonable assurances from the third

party that (i) the information will be held confidentially and used or further disclosed only as Required By Law or for the purpose for which it was disclosed to the third party, and (ii) the third party will notify Business Associate of any instances of which it becomes aware in which the confidentiality of the information has been breached; and (c) provide Data Aggregation services to Covered Entity.

2.3 Prohibited Access and Use of Certain PHI by Business Associate. Business Associate understands and agrees that it will not access or use any PHI of any patient except for those patients whose accounts have been assigned to Business Associate, and it will further limit access to that PHI that is necessary to the activities undertaken by Business Associate on behalf of Covered Entity.

2.4 Obligations of Covered Entity. Covered Entity will:

2.4.1 Obtain the permission of Individuals to Use or Disclose such Individual's PHI or Electronic PHI to Business Associate as necessary for Business Associate to perform its Services under the Underlying Contract.

2.4.2 Notify Business Associate of any limitation in Covered Entity's notice of privacy practices under 45 CFR § 164.520, to the extent that such limitation may affect Business Associate's Use or Disclosure of PHI.

2.4.3 Notify Business Associate of any changes in, or revocation of, the permission by an Individual to Use or Disclose such Individual's PHI, to the extent that such changes may affect Business Associate's Use or Disclosure of PHI.

2.4.4 Notify Business Associate of any restriction to the Use or Disclosure of PHI to which Covered Entity has agreed or by which Covered Entity is required to abide under 45 CFR § 164.522, to the extent that such restriction may affect Business Associate's Use or Disclosure of PHI.

2.4.5 Not request Business Associate to Use or Disclose PHI in any manner that would not be permissible under Subpart E of 45 CFR Part 145 if done by Covered Entity, except as otherwise allowed under this Agreement.

2.5 Effect of Changes to the Law. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the Privacy Rule, the Security Rule, HIPAA, HITECH Act, and applicable state privacy and security laws and regulations.

3. EFFECTIVE DATE; TERMINATION.

3.1 Effective Date. Each term and condition of this Agreement shall be effective on the compliance date applicable to Covered Entity under the Privacy Rule, unless such term or condition relates to Electronic PHI only, in which event such term or condition shall be effective on the later of (a) the date set forth in the first paragraph of this Agreement, or

(b) the compliance date applicable to Covered Entity under the HITECH Act. This Agreement shall continue in effect unless terminated as provided in Sections 3.2 or 3.3.

3.2 Termination without Cause. This Agreement shall terminate when (a) all of the PHI obtained from Covered Entity or created or obtained by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity, or (b) each Underlying Contract has terminated or expired, provided that if it is infeasible to return or destroy the PHI, protections shall be extended to such information in accordance with Section 2.1.17. of this Agreement.

3.3 Termination for Cause. Upon Covered Entity's determination that there has been a material breach by Business Associate of this Agreement, Covered Entity may either:

3.3.1. Provide an opportunity for Business Associate to cure the breach or end the violation, and terminate this Agreement and, at its option, one or more Underlying Contracts, if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity; or

3.3.2. Immediately terminate this Agreement and, at its option, one or more Underlying Contracts, if Business Associate has breached a material term of this Agreement.

4. MISCELLANEOUS.

4.1 Regulatory References: A reference in this Agreement to a section of the Privacy Rule, Security Rule, HIPAA, or HITECH Act means the section as in effect or as amended.

4.2 Interpretation. As of the Effective Date, the terms of this Agreement shall prevail in the case of any conflict with the terms of any Underlying Contract to the extent and only to the extent of the conflict and only to the extent that it is reasonably impossible to comply with both the terms of the Underlying Contract and the terms of this Agreement.

4.3 No Third-Party Beneficiaries. Nothing in this Agreement shall confer upon any person other than the Parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.

4.4 Indemnification. Business Associate shall indemnify, hold harmless and defend Covered Entity from and against any and all claims, losses, liabilities, costs and other expenses incurred as a result of, or arising in connection with, any breach by Business Associate of the terms of this Agreement.

4.5 Reimbursement of Notification Expenses. In the event of a Breach, pursuant to Section 2.1.9 by the Business Associate, the Business Associate will

reimburse the Covered Entity for all reasonable costs associated with all statutorily prescribed notifications related to the Business Associate's Breach of Electronic PHI.

4.6 Right to Audit. Business Associate understands and agrees that its access to PHI stored in databases and information systems at Covered Entity is subject to review and audit by Covered Entity at any time, that remote audits of such access may occur at any time, that on-site audits of such access will be conducted during regular business hours, and that any review or audit may occur with or without prior notice by Covered Entity.

4.7 Notices: Any notice or document required or permitted to be given under this Agreement shall be deemed to be given on the date such notice is (i) deposited in the United States mail, postage, prepaid, certified mail, return receipt requested or (ii) deposited with a commercial overnight delivery service, to the principal business address of the recipient or such other address or addresses as the Parties may designate from time to time by notice satisfactory under this section.

4.8 Limitation on Subcontracting. **Business Associate understands and agrees that it will not assign, delegate, or subcontract any of its rights or obligations under this Agreement to individuals or entities residing outside the United States.** Business Associate further understands and agrees that it will not assign, delegate or subcontract any of its rights or obligations under this Agreement to individuals or entities residing within the United States without the prior written consent of Covered Entity's HIPAA Privacy Officer.

4.9 Governing Law; Jurisdiction. This Agreement shall be governed by the laws of the **State of Texas** and shall be enforceable in the courts of the **State of Texas**, or in the **Houston Division of the U.S. District Court for the Southern District of Texas**. The Parties irrevocably submit to the exclusive jurisdiction of such courts.

IN WITNESS WHEREOF, each of the undersigned has caused this Agreement to be executed in its name and on its behalf by its duly authorized representative.

COVERED ENTITY

By:

Name:

Title:

Date:

**BUSINESS ASSOCIATE
ALLIANCE FOR PHARMACY COMPOUNDING**

By:

Name: Scott Brunner
Title: Chief Executive
Date:

Please return completed data use agreements and contact forms to Missy Wigley at info@a4pc.org.