# 340B DIRECT AMENDED AND RESTATED CONTRACT PHARMACY SERVICES AGREEMENT

This 340B Direct Contract Pharmacy Services Agreement ("Agreement"), by and between County of San Mateo ("Covered Entity") and Albertsons Companies, Inc., including its subsidiaries that own and/or operate the participating Pharmacy locations listed in Exhibit D attached hereto ("Pharmacy"), is made and will take effect on the date listed in Section 5 below (the "Effective Date").

WHEREAS, Covered Entity participates in the 340B Program (defined below);

WHEREAS, Covered Entity currently contracts with Pharmacy ("Original Agreement(s)") previously executed by and between County of San Mateo and Safeway Inc. on December 13, 2016 to provide the services of a contract pharmacy to serve patients eligible to receive 340B-discounted drugs ("Covered Entity Patients"), as permitted under 75 Fed. Reg. 10272 (March 5, 2010);

WHEREAS, pursuant to 75 Fed. Reg. 10272, in addition to contracting with a single pharmacy for each clinical site, Covered Entities may pursue arrangements that include multiple pharmacies, provided that (1) there is a written agreement in place that meets 340B Program requirements, as articulated in 340B Program multiple contract pharmacy guidance; (2) the operation of the arrangement continues to meet all 340B Program requirements and does not create diversion of 340B Drugs or duplicate discounts; (3) the arrangements are one of the following models either individually or in combination: (i) the use of multiple contract pharmacy service sites and/or (ii) the utilization of a contract pharmacy/pharmacies to supplement in-house pharmacy services; and (4) the arrangement involves a single identifiable Covered Entity and does not include a network; and

WHEREAS, Pharmacy and Covered Entity wish to amend and restate the terms of the Original Agreement(s) to reflect Covered Entity's participation in Pharmacy's 340B Direct Program as set forth herein.

NOW, THEREFORE, the Parties agree as follows:

#### 1. Definitions.

- **a.** "340B Direct Program" shall mean the services offered by Pharmacy relating to administration and management of 340B Program functions as further specified in this Agreement.
- **b.** "340B Dispensing Fee(s)" shall mean those fees due to Pharmacy pursuant to this Agreement as set forth on **Exhibit A**, as may be modified from time to time.

- c. "340B Drugs" shall be defined in accordance with applicable laws and guidance at 42 U.S.C. § 256b(b), 42 U.S.C. § 1396r-8(k), and 59 Fed. Reg. 25,110 (May 13, 1994).
- **d.** "340B Program" shall be defined as part of the 1992 Veteran's Health Care Act, which created Section 340B of the Public Health Services Act, allowing certain "Covered Entities" to purchase outpatient prescription drugs for their patients at favorable discounts from drug manufacturers who enter into pharmaceutical pricing agreements with the Department.
- **e.** "340B Program Administrator" shall mean the third party 340B services provider, if any, engaged by Covered Entity to manage or administer its 340B program and contract pharmacy arrangements.
- **f.** "Agreement" shall mean this 340B Direct Contract Pharmacy Services Agreement and accompanying exhibits, if any, as may be amended from time to time.
- **g.** "Brand Drug" means a prescription drug that is categorized with a First DataBank multisource code of "B" or "N" or a corresponding indicator from a similar published compendium of drug information.
- **h.** "Covered Entity" shall mean the legal entity identified in this Agreement, including all of its 340B eligible site locations identified in **Exhibit C** attached hereto.
- i. "Covered Entity Patients" shall mean those individuals who satisfy HRSA's patient definition criteria at 61 Fed. Reg. 55,156-58 (Oct. 24, 1996), as may be amended from time to time.
- j. "Department" shall mean the United States Department of Health and Human Services.
- **k.** "Generics" or "Generic Drug" means a prescription drug that is categorized with a First DataBank multisource code of "G" or a corresponding indicator from a similar published compendium of drug information.
- **I.** "HRSA" shall mean the Health Resources and Services Administration, which is the agency within the Department that oversees activities of the Office of Pharmacy Affairs.
- **m.** "Insured Claim" shall mean a claim for a 340B Drug that is adjudicated at the point of sale in accordance with contracted rates between the Pharmacy and any applicable third-party payor (i.e. Pharmacy Benefits Manager, plan or self-funded employer).
- **n.** "NDC" or "NDC-11" shall mean National Drug Code or the unique 11-digit product identifier assigned by the US Food and Drug Administration to all prescription drugs used in the United States containing 3 segments including the labeler code, the product code, and the package code.

- o. "Non-Replenishable Items" shall mean (i) any discontinued items, or items no longer available with the same NDC-11 as the originally dispensed item; or (ii) slow moving items, meaning any 340B Drug (at the NDC-11 level) which, at the time of the applicable True-up, has not been captured (or at Pharmacy's option, has not been replenished) within the immediately preceding ninety (90) days.
- **p.** "OPA" shall mean the Office of Pharmacy Affairs, which is within HRSA and which administers the 340B Program.
- **q.** "Parties" or "Party" shall mean the signatories to this Agreement, which are the Covered Entity and Pharmacy.
- r. "Pharmacy" shall mean the legal entity identified in this Agreement. If there is more than one Pharmacy location that shall be utilized by Covered Entity in order to serve Covered Entity Patients, each Pharmacy site shall be identified in an **Exhibit D** attached hereto and incorporated herein by reference.
- s. "Tracking System" shall mean the system for identifying and monitoring the use of drugs through all phases of the Parties' involvement with such drugs, including the ordering of 340B Drugs, the receipt of 340B Drugs, Covered Entity's payment for 340B Drugs, internal transfers of 340B Drugs within the Pharmacy, Pharmacy's preparation and dispensing of 340B Drugs, and Pharmacy's billing of the Covered Entity Patient or third-party insurer for the 340B Drugs on behalf of Covered Entity.
- t. "Uninsured Claim" shall mean any claim that is adjudicated or paid at the point of sale in accordance with an uninsured 340B Program maintained by the Covered Entity and/or its 340B Program Administrator, including any subsidized or unsubsidized uninsured program.

# 2. Essential Covered Entity Compliance Elements.

- a. Maintaining Title. Covered Entity shall purchase the 340B Drugs and shall assume all responsibility for establishing the price of the 340B Drugs subject to applicable Federal, State, and local laws. Under the virtual inventory replenishment model, the Covered Entity shall maintain title to 340B Drugs until they are delivered to the Pharmacy and used to replenish retail inventory dispensed by the Pharmacy, at which time title to such drugs will transfer to the Pharmacy. Covered Entity shall ensure that the transaction history, transaction information and transaction statement required by the Drug Supply Chain Security Act (DSCSA) (Title II of the Drug Quality and Security Act) for such drugs is provided to Pharmacy at the time of transfer.
- **b. Ship To, Bill To Agreement.** A "ship to, bill to" procedure shall be used by the Parties, pursuant to which the Covered Entity or Pharmacy, on behalf of the Covered Entity through the 340B Direct Program, shall order on Covered Entity's behalf through the

340B Direct Program, 340B Drugs directly from the drug manufacturer, a designated sales representative, or a drug wholesaler. Covered Entity, or Pharmacy through the 340B Direct Program, shall arrange for Covered Entity to be billed directly for purchased 340B Drugs. Covered Entity shall arrange for the wholesaler to ship the 340B Drugs directly to Pharmacy.

- **c. Pharmacy Services.** Pharmacy shall perform the following services (collectively, the "Pharmacy Services").
  - 1) Dispense 340B Drugs to Covered Entity Patients in accordance with all applicable State and Federal statutes and regulations;
  - 2) Conduct patient drug utilization review;
  - 3) Maintain patient drug profiles in accordance with Pharmacy's usual business practices; and
  - 4) Counsel and advise Covered Entity Patients consistent with the rules, limitations, and privileges incident to the pharmacy-patient relationship.

# d. Inventory Replenishment.

- 1) Replenishable Items. Covered Entity or Pharmacy, on behalf of Covered Entity through the 340B Direct Program, shall order for delivery to Pharmacy all 340B Drugs which have been determined to be eligible and have reached a full package size but have not yet been delivered to Pharmacy. 340B Drugs dispensed to Covered Entity Patients shall be replenished at the NDC-11 level. Covered Entity and Pharmacy each agree that 'Schedule II' controlled substances will not be dispensed under this Agreement in connection with Covered Entity's 340B Program.
- 2) Non-Replenishable Items.
  - a. <u>True-up</u>. Pharmacy, in connection with the 340B Program Administrator, shall conduct a "True-up" of Non-Replenishable Items, no less than once per calendar quarter. True-ups shall be conducted as follows:
    - i. <u>True-up Charges</u>: The Covered Entity shall reimburse the Pharmacy for all Non-Replenishable Items at the then current "Estimated Acquisition Cost" as defined and calculated in accordance with the then current **Exhibit A**.
    - ii. <u>Partial Replenishment</u>. Any True-up adjustments for less than the full amount of 340B Drugs dispensed in connection with applicable Captured Claims shall be made on a pro rata basis.
    - iii. <u>Uncaptured Uninsured Claims</u>: The Covered Entity shall reimburse the Pharmacy (or if applicable be paid by the Pharmacy) for all

Uninsured Claims which are not Captured ("Uncaptured Uninsured Claim(s)") at the "Assumed Reimbursement Rate" as defined below, minus the amount paid by the applicable Covered Entity Patient at the 'Point of Sale.' For the purposes of such Uncaptured Uninsured Claims the Assumed Reimbursement Rate for each applicable drug shall be: (a) SWP-15%, plus a \$3.00 dispensing fee for Brand Drugs; and (b) SWP-65%, plus a \$3.00 dispensing fee for Generic Drugs.

- **e. Freedom of Choice.** Covered Entity shall inform all Covered Entity Patients that if he or she does not elect to use Pharmacy, Covered Entity will provide the Covered Entity Patient with his or her prescription form and the Covered Entity Patient is then free to fill the prescription using the pharmacy provider of his or her choice.
- **f. Tracking System.** The 340B Direct Program establishes and maintains a Tracking System using customary business records, suitable to prevent the diversion of 340B Drugs to individuals who are not Covered Entity Patients. The Tracking System allows Covered Entity to make periodic comparisons of Covered Entity prescribing records with Pharmacy dispensing records to detect potential irregularities.
- **g. Patient Verification; Prohibition Against Diversion.** Covered Entity is solely responsible for identifying and verifying Covered Entity Patient eligibility, as defined by HRSA guidelines, and for providing that same information to Pharmacy. Covered Entity and Pharmacy shall not resell or transfer 340B Drugs to any individual or any other entity who is not a Covered Entity Patient.
- h. Prohibition Against Duplicate Discounts. Neither Party shall use 340B Drugs to dispense 'fee for service' Medicaid prescriptions, unless Covered Entity, Pharmacy and the State Medicaid program have established an arrangement to prevent duplicate discounts. Any such arrangement shall be reported to HRSA by the Covered Entity. At Covered Entity's election, by written notice, Managed Medicaid prescription claims shall be excluded from the 340B Program under the terms of this Agreement, to the extent that Covered Entity or its 340B Program Administrator provides Pharmacy or its designee with a BIN/PCN exclusion list for applicable Managed Medicaid programs. Notwithstanding the foregoing, Pharmacy shall have no responsibility for identifying Managed Medicaid prescriptions, and shall be entitled to rely on the Covered Entity to identify such patients as part of its determination of whether a patient is a Covered Entity Patient. For the avoidance of doubt, fee-for-service Medicaid is automatically excluded from the 340B Program under this Agreement.
- i. Maintaining Compliance. Covered Entity and Pharmacy will identify the necessary information for the Covered Entity to meet its ongoing 340B Program compliance obligations. Pharmacy will make such information (including, but not limited to customary business reports), as well as additional reports as agreed to by the Parties,

- available under the 340B Direct Program to enable an annual independent audit as well as quarterly self-audit reviews performed by the Covered Entity.
- **j.** Outside Audits. Covered Entity and Pharmacy understand that they are subject to audits by outside parties (the Department and participating manufacturers) of records that directly pertain to the Covered Entity's compliance with the drug diversion prohibition and the prohibition against duplicate discounts.
- **k.** Access to Agreement. Upon written request to the Covered Entity, a copy of this Agreement will be provided to OPA.

# 3. Other Pharmacy and/or Covered Entity Responsibilities.

- **a. Receipt of 340B Drugs.** Pharmacy is responsible for the receipt of 340B Drugs purchased by Covered Entity. Upon receipt of 340B Drugs, Pharmacy shall compare all shipments received on behalf of Covered Entity and confirm that the shipments conform to the related orders of 340B Drugs. If Pharmacy should find a discrepancy between the shipment and order of 340B Drugs, Pharmacy shall inform the wholesaler who shipped the Covered Entity's replenishment order within five (5) business days of this discrepancy.
- b. Central Inventory Replenishment, Maintenance, and Ordering. Pharmacy shall maintain systems and processes to track and report inventory dispensed to Covered Entity Patients on an aggregated basis across all participating Pharmacy locations, as listed in Exhibit D. Pharmacy will provide real time access and reporting related to applicable inventory levels and required replenishment. The 340B Direct Program will track all virtual inventory levels and manage the ordering of applicable replenishment inventory. For all Captured Claims, the Covered Entity shall purchase and replenish applicable inventory due to Pharmacy in accordance with the reported Captured Claims and the replenishment orders generated by the 340B Direct Program.
- c. Eligibility and Claim Capture. When presented with a valid prescription from a Covered Entity Patient, Pharmacy shall adjudicate the claim and dispense the drugs to such Covered Entity Patient per the terms of the prescription order, this Agreement and the standard practices of the 340B Direct Program. Subject to Covered Entity's ongoing cooperation and compliance, the terms of this Agreement and the requirements of the 340B Direct Program, including without limitation the provision of accurate "Eligibility Data," as defined below, Pharmacy shall maintain systems and processes to enable Pharmacy to identify which pharmacy claims at participating locations were for Covered Entity Patients and which meet the other requirements of the 340B Direct Program, and when appropriate, capture such claims for the benefit of the Covered Entity (each a "Captured Claim"). In no event, without Pharmacy's prior written authorization, shall Pharmacy be required to capture any claims for a Covered Entity after thirty (30) days following the date that the underlying drug was sold to the applicable Covered Entity Patient.

- d. Eligibility Data. In accordance with the requirements of the 340B Direct Program, Covered Entity shall provide Pharmacy and/or its designee with Eligibility Data in a manner and frequency acceptable to Pharmacy, as determined during the 340B Direct Program implementation process. For purposes of this Agreement, the term "Eligibility Data" shall include, without limitation, Covered Entity Patient information, prescriber and provider information, and such other information and data reasonably requested by Pharmacy.
- e. Billing Third-Party Insurers. Pharmacy shall be responsible for billing applicable third-party insurers for 340B Drugs purchased by Covered Entity for Covered Entity Patients with third party coverage, and for billing Covered Entity Patients for insurance co-payments, where applicable with respect to Captured Claims. The Parties shall establish procedures for Pharmacy to follow (e.g. use of a sliding fee schedule, refer patient to Covered Entity's patient assistance program, etc.) with respect to Covered Entity Patients who do not have prescription drug coverage and are unable to pay for their 340B Drugs.
- f. Invoices and Payments. Under the 340B Direct Program, Pharmacy will prepare and electronically deliver an invoice to Covered Entity, which identifies all monies owed by or to Pharmacy ("Invoice"). For each Captured Claim, Pharmacy shall be entitled to a 340B Dispensing Fee for Pharmacy Services provided hereunder and Pharmacy shall reimburse (or if applicable, charge) the Covered Entity as specified in Exhibit A. The Pharmacy shall remit applicable payments due to the Covered Entity for Captured Claims for which Pharmacy has been paid as specified in Exhibit A. At the request and direction of the Covered Entity, Pharmacy shall also remit applicable administrative fee payments to Covered Entity's independent 340B Program Administrator, if any. Such remittances shall be in the manner indicated by the Covered Entity as set forth in Exhibit B.
- g. Maintenance of Pharmacy Services Records. On behalf of Covered Entity, Pharmacy shall maintain all pertinent records relating to the Pharmacy Services associated with 340B Drugs and Covered Entity Patients as well as the 340B Direct Program, in accordance with applicable Federal, State, and local laws and regulations, including but not limited to the Federal Standards for the Privacy of Individually Identifiable Health Information. Pharmacy shall maintain all auditable records for a period consistent with all applicable Federal and State laws.
- h. Access to Business Records. Under the 340B Direct Program, Pharmacy shall provide Covered Entity with 24/7 access (subject to reasonable downtime for maintenance) to the 340B Direct Program reporting and information portal to enable Covered Entity to receive and access, regular reports, detailed Captured Claim information, virtual inventory levels, and order information reasonably necessary for Covered Entity to ensure that Pharmacy is in compliance with applicable Federal, State, and local laws, regulations, and requirements.

- i. Maintenance of Account Records. Pharmacy shall ensure that all reimbursement accounts and dispensing records, and any and all other pertinent records relating to Pharmacy's responsibilities and duties under this Agreement, are maintained by Pharmacy separately from Pharmacy's own operations and will be made available to Covered Entity, HRSA, and manufacturers in the case of an audit.
- **j. Inspection of Records.** Upon request, Covered Entity and Pharmacy shall disclose or permit inspection of any records or information relating to this Agreement, when necessary to comply with audits or investigations conducted by the Federal or State governments.
- k. Drug Manufacturer Audits. Upon request, Pharmacy shall provide reasonable access by a drug manufacturer that sells 340B Drugs to Covered Entity to pertinent records and materials for purposes of any audits conducted by the drug manufacturer relating to 340B Drugs dispensed by Pharmacy pursuant to this Agreement, in accordance with manufacturer audit guidelines as set forth at 61 Fed. Reg. 65406-65413 (December 12, 1996). In the event of a drug manufacturer audit, Covered Entity will, to the extent practicable, provide two (2) business days' advance written notice to Pharmacy's central office as set forth in Section 24 and shall coordinate with Pharmacy to minimize any disruption to Pharmacy's operations that may be caused by such audit.
- **l.** Access to Program Information. Upon request, Covered Entity shall provide authorization and reasonable access for Pharmacy to pertinent records and materials necessary for the administration of the 340B Direct Program under this Agreement including without limitation, wholesaler pricing, ordering, and inventory information (i.e. 810, 832 and 855 files) and other files and information reasonably necessary to enable Pharmacy to perform its services under this Agreement and to meet its compliance obligations.

#### 4. Ongoing Responsibility of Covered Entity to Ensure Compliance.

- a. Eligibility Data. Covered Entity shall be solely responsible for its 340B Program compliance, including ensuring the accuracy of its Eligibility Data, and Pharmacy is entitled to rely on the accuracy and completeness of this information. Covered Entity shall indemnify Pharmacy and its affiliates, employees, officers and directors, from any costs, losses or damages arising from Covered Entity's failure to provide accurate and timely data. Covered Entity shall be responsible for maintaining its eligibility and all applicable registration requirements as a 340B Covered Entity and shall immediately notify Pharmacy of any change in status or the status of any registered contract pharmacy relationship with Pharmacy.
- **b. Compliance.** Covered Entity is responsible for ensuring that the process for distribution of 340B Drugs complies with 340B Program requirements to ensure against the diversion of 340B Drugs and prevent duplicate discounts. In accordance

- with 340B Program guidance, Covered Entity may therefore undertake an annual, independent audit as well as quarterly self-audit reviews for the purpose of ensuring that the prohibitions against diversion and duplicate discounts are not breached.
- c. Audit Right and Notice. Upon no less than two (2) business days advance written notice to Albertsons Companies c/o 340BDirect set forth in Section 24, and subject to all applicable State and Federal laws regarding the confidentiality of records, Covered Entity and its authorized representatives shall have the right, for the term of this Agreement (or such longer period required by law), to review, audit, examine, and receive copies of any of the Pharmacy's Records related to the determination of compliance with HRSA 340B guidance on the avoidance of duplicate discounts and drug diversion. Notice shall include Covered Entity's HRSA identification number, prescription number, date of service, pharmacy store number(s) and physical address(es). Except as otherwise approved by Pharmacy this right shall be limited to one (1) year after the date of dispensing.
- d. Audited Records. For purposes of any such audit, the term "Pharmacy's Records" shall consist of the following records: (i) prescriptions related to 340B transactions under this Agreement, (ii) evidence that the prescription was filled, picked-up or delivered, and the applicable copayments or deductible payments were made; and (iii) claims information for the purposes of determining the existence of drug diversion or duplicate discounts. Unless the audit reveals a material issue, Covered Entity audits shall be limited to no more than twenty (20) physical copies of prescriptions per audit.
- e. Remote Access to Pharmacy Records. The Parties acknowledge that the primary Pharmacy Records are electronically stored in Pharmacy's 340B Direct system and can be made available to the Covered Entity remotely. To the fullest extent practicable, audits shall be conducted remotely and, to the extent commercially reasonable, Pharmacy shall provide Covered Entity or its authorized representatives with electronic copies or electronic access to any reasonably required Pharmacy Records requested. To the extent that the parties reasonably determine that an onsite audit is required, Covered Entity shall conduct such audit during regular pharmacy business hours, in a manner and at a time to minimize disruption to such pharmacy's business operations, and subject to the provisions of this Agreement. In no event shall Covered Entity conduct an onsite audit more than once per calendar year at a given pharmacy location.
- **f.** Audit Results. A written result of all audits shall be forwarded to Pharmacy within thirty (30) days of said audit. Pharmacy shall have thirty (30) days from the date of receipt of notification of audit results to address any compliance concerns raised by the audit and submit additional documentation for Covered Entity's consideration. Audit results may not be extrapolated; hence any determination must be specifically related to an actual claim.

- **g.** Auditor and Audit Method. Covered Entity may maintain sole discretion over the selection of an independent, outside auditor to perform any audits referenced in this Section 4. Such auditor shall have experience auditing pharmacies for 340B Program compliance. Covered Entity shall determine, in consultation with the independent auditor, the methodology to be utilized in performing the audit.
- h. Remedial Action. In the event that Covered Entity determines that 340B Drug diversion or duplicate discounts have occurred or that it is otherwise unable to comply with its responsibility to ensure reasonable compliance, it must take immediate remedial action to ensure compliance and when necessary notify OPA regarding such compliance problems and actions taken to remedy those problems.
- i. Uninsured Program and Covered Entity Patient Cards. If Covered Entity offers an uninsured 340B Program for the processing of Uninsured Claims under the Agreement, Covered Entity shall issue Covered Entity Patients who are eligible for the uninsured 340B Program a third-party card to facilitate billing of Uninsured Claims at the point of sale ("Covered Entity Patient Card"). Covered Entity will be responsible for determining patient eligibility for participation in the uninsured 340B Program and Pharmacy shall be entitled to rely on the Covered Entity Patient Card adjudication response at point of sale.
- **Term and Termination.** The Term of this Agreement shall be for five years commencing on January 1, 2023 (Effective Date) through December 31, 2027.
  - **a.** In the event either Party materially breaches the terms of this Agreement, the non-breaching Party may terminate this Agreement upon thirty (30) days' prior written notice to the other, specifying the nature of such breach and such breach remains uncured at the end of such thirty (30) day period.
  - **b.** Either Party may terminate this Agreement at any time, with or without cause, by giving the other Party sixty (60) days' prior written notice.
  - **c.** The Parties may terminate this Agreement at any time by mutual consent.
  - **d.** Upon termination or expiration of this Agreement, the Parties shall remain responsible for obligations which accrued prior to the date of termination or during any transition period, including, but not limited to Covered Entity's obligations to pay fees due Pharmacy for Pharmacy Services rendered and Pharmacy's obligation to remit required payments to Covered Entity. The Parties shall reconcile and pay all fees or payments due as soon as commercially practicable, but no later than ninety (90) days following termination of this Agreement unless otherwise agreed to by the Parties in writing.

# 6. Confidentiality.

- a. The Parties shall work in good faith to prevent the unauthorized use and/or disclosure of Confidential Information received by a Party (the "Receiving Party") from the other Party (the "Disclosing Party"). The term "Confidential Information" includes any information that a Party knows or reasonably should know is intended to be confidential or proprietary by the other Party, regardless of whether the information is marked as such and shall specifically include all forms, reports, systems and technology, financial information and financial terms and pricing schedules, policies, programs, and operational procedures of a Party used or produced by either Party pursuant to this Agreement, as well as the terms of this Agreement. The Receiving Party shall establish and maintain, throughout the term of this Agreement, policies and procedures designed to prevent the unauthorized use and/or disclosure of the Disclosing Party's Confidential Information, which policies and procedures shall establish at least the same level of care as used to protect the Receiving Party's own Confidential Information and no less care than what is considered reasonable. Additionally, the Receiving Party agrees to maintain and transfer all Confidential Information disclosed under this Agreement in a manner consistent with all applicable laws, including, but not limited to the Health Insurance Portability and Accountability Act of 1996, and its implementing regulations (45 CFR Parts 160 and 164) ("HIPAA").
- b. Notwithstanding the foregoing, Confidential Information may be disclosed to either Party's employees or contractors or to any third party (an "Authorized Representative") as reasonably necessary to carry out the purposes of this Agreement or the administration of the receiving Party's business and operations; provided such Authorized Representative has agreed to be bound by obligations of non-disclosure and non-use regarding the Confidential Information that are at least as comprehensive as the obligations contained herein. Each Party shall be responsible for any breach of this Agreement by any Authorized Representative to which it discloses Confidential Information under this Agreement.
- c. Confidential Information shall not include any information which: (i) is or becomes generally available to the public other than as a result of disclosure by the Receiving Party, its agents, representatives or employees; (ii) was within the Receiving Party's possession on a non-confidential basis prior to disclosure by the Disclosing Party; (iii) the Receiving Party is required by law or judicial order to disclose such information, provided that the Receiving Party shall promptly notify the Disclosing Party of such requirement so that the Disclosing Party may seek an appropriate protective order or otherwise seek to protect the confidentiality of such information.
- **d.** Each Party shall retain full ownership rights of its Confidential Information disclosed hereunder, including derivative works based on or otherwise incorporating such Confidential Information. Ownership rights shall include, but are not limited to, all rights associated with trade secrets, copyrights, trademarks, and patents.

- e. Upon termination of this Agreement, or upon the written request of the Disclosing Party, the Receiving Party shall return all written or other physical or electronic embodiments of Confidential Information to the Disclosing Party, together with all copies thereof or copies of any part thereof as shall then be in Receiving Party's possession. If return of all written or other physical or electronic embodiments of Confidential Information is not commercially practical, then at the direction of the Disclosing Party, the Receiving Party shall account for all Confidential Information and either: (i) destroy such Confidential Information; or (ii) continue to hold such Confidential Information in a secure manner until return or destruction is possible. Notwithstanding the foregoing, the return or destruction of Confidential Information shall not include information that must be retained by the Receiving Party under law for auditing or other purposes or as otherwise provided in this Agreement. In any event, such Confidential Information shall at all times be maintained by the Receiving Party in a manner consistent with the terms of this Agreement.
- **f.** Nothing in this agreement shall limit the Covered Entity's responsibilities and legal ability to produce records pursuant to the California Public Records Act.

#### 7. Indemnification.

- a. Pharmacy shall indemnify, defend and hold Covered Entity harmless from any and all liability, loss, claim, lawsuit, cost, damage or expense whatsoever (including reasonable attorney's fees) arising out of, incident to or in any manner occasioned by the negligence or willful misconduct of Pharmacy or any of its employees, agents, contractors, or subcontractors; except that Pharmacy shall have no duty to indemnify, defend, or hold Covered Entity harmless for any liability, loss, claim, lawsuit, cost, damage or expense whatsoever (including reasonable attorney's fees) arising out of, incident to or in any manner occasioned by Covered Entity's provision of a prescription for 340B Drugs to an individual who is not a Covered Entity Patient or other inappropriate diversion of 340B Drugs by Covered Entity.
- **b.** Covered Entity shall indemnify, defend and hold Pharmacy harmless from any and all liability, loss, claim, lawsuit, cost, damage or expense whatsoever (including reasonable attorney's fees) arising out of, incident to or in any manner occasioned by the negligence or willful misconduct of Covered Entity or any breach of duty or responsibility under this Agreement by Covered Entity or any of its employees, agents, contractors, or subcontractors.
- c. A Party seeking indemnification pursuant to this Section (the "Indemnified Party"), shall notify the other Party (the "Indemnifying Party") promptly upon becoming aware of any action to which such indemnification may apply. The Indemnifying Party shall have the right to assume and control the defense of the action at its own expense; provided that the Indemnifying Party may not make any settlement that requires any payment by the Indemnified Party or admission of wrongdoing from the Indemnified Party without the Indemnified Party's prior written consent. If the right to assume and

control the defense of any such action is exercised, the Indemnified Party shall have the right to participate in such defense. If the Indemnifying Party does not reasonably assume the defense of the action, the Indemnified Party may defend the action and shall be indemnified for reasonable costs of such defense.

d. EXCEPT TO THE EXTENT THAT LIABILITY ARISES FROM A PARTY'S INDEMNITY OBLIGATIONS SPECIFIED HEREIN, IN NO EVENT SHALL EITHER PARTY BE LIABLE UNDER THIS AGREEMENT (WHETHER AN ACTION IN CONTRACT OR IN TORT OR BASED ON A WARRANTY OR OTHERWISE) FOR LOSS OF PROFITS, REVENUE, OR ANY INDIRECT, INCIDENTAL, PUNITIVE, SPECIAL OR CONSEQUENTIAL DAMAGES INCURRED BY THE OTHER PARTY OR ANY THIRD PARTY, EVEN IF THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

#### 8. Insurance.

- a. General Requirements. With respect to the performance of their respective obligations under this Agreement, Covered Entity and Pharmacy shall each maintain general liability insurance with limits of not less than one million dollars (\$1,000,000) per occurrence and three million dollars (\$3,000,000) in the aggregate per policy year. Pharmacy shall maintain Druggist liability of not less than one million (\$1,000,000) per occurrence and three million dollars (\$3,000,000) in the aggregate per policy year. Pharmacy shall furnish Covered Entity with certificates of insurance evidencing the required coverage, and there shall be a specific contractual liability endorsement extending Pharmacy's coverage to include the contractual liability assumed by Pharmacy pursuant to this Agreement. These certificates shall specify or be endorsed to provide that thirty (30) days' notice must be given, in writing, to Covered Entity of any pending change in the limits of liability or of any cancellation or modification of the policy.
- b. Workers' Compensation and Employer's Liability Insurance. Pharmacy shall have in effect during the entire term of this Agreement workers' compensation and employer's liability insurance providing full statutory coverage. In signing this Agreement, Pharmacy certifies, as required by Section 1861 of the California Labor Code, that (a) it is aware of the provisions of Section 3700 of the California Labor Code, which require every employer to be insured against liability for workers' compensation or to undertake self-insurance in accordance with the provisions of the Labor Code, and (b) it will comply with such provisions before commencing the performance of work under this Agreement.

In the event of the breach of any provision of this Section, or in the event any notice is received which indicates any required insurance coverage will be diminished or canceled, Covered Entity, at its option, may, notwithstanding any other provision of this Agreement to the contrary, immediately declare a material breach of this Agreement and suspend all further work and payment pursuant to this Agreement.

- 9. **Arbitration.** Any and all disputes, controversies or claims (including without limitation tort claims, requests for provisional remedies or other interim relief and issues as to arbitrability of any matter) arising out of, in connection with, or relating to this Agreement, or the breach thereof, that cannot be settled through negotiation shall be settled by arbitration administered by JAMS pursuant to its Comprehensive Arbitration Rules and Procedures; provided, however, that the provisions contained in this Agreement shall govern over any conflicting rules that may now or hereafter be contained in the JAMS rules. The Parties agree that the Expedited Procedures set forth in JAMS Comprehensive Rules 16.1 and 16.2 shall be employed. Any dispute under \$250,000.00 (or such other amount allowed by JAMS) shall be handled in accordance with the JAMS Streamlined Arbitration Rules and Procedures. The arbitration shall be held in San Mateo, California before a single arbitrator and commence within sixty (60) days of the appointment of the arbitrator by JAMS. The arbitrator shall render an award no later than ten (10) days after the conclusion of such hearing, unless otherwise mutually agreed in writing by the Parties. Each Party shall bear its own costs, fees, and expenses, and neither Party shall be entitled to an award of attorney's fees, expert witness fees, arbitrator's fees, reporter's fees, filing fees, or any other cost or expense associated with the arbitration. The award of the arbitrator will be final and binding on the Parties, and judgment upon such award may be entered in any court having jurisdiction thereof. The arbitration proceeding provided for herein is a private proceeding and neither Party shall disclose or publicize the decision of the arbitrator other than as required by law. The arbitrator will not have the power to alter, amend, or otherwise affect the terms of the dispute resolution provisions set forth in this section or any other provisions contained in this Agreement
- 10. Compliance with Applicable Law. The Parties shall comply with all Federal and State laws, regulations and rules governing the practice of such Party under this Agreement. The Parties shall not take any action that would violate State or Federal anti-kickback laws, including, without limitation, those provided for in Section 1128B of the Social Security Act (42 U.S.C. 1320a-7b). The Parties acknowledge that during the course of fulfilling their respective obligations under this Agreement each shall comply with HIPAA; the requirements of all insurance commissioner regulations implementing Title V of the Gramm-Leach-Bliley Act (15 USC § 6801 et seq.) that are applicable to the Parties relationship; and Title XIII of the American Recovery and Reinvestment Act of 2009 and its implementing regulations ("ARRA"). The Parties recognize that they are each healthcare providers within the meaning of HIPAA. The Parties acknowledge that as covered entities under HIPAA, each must comply with HIPAA and applicable state law concerning the confidentiality, privacy, and security of all Covered Entity Patient information, including but not limited to Protected Health Information as defined in 45 CFR 160.103. Covered Entity represents and warrants: (a) the 340B Program Administrator is a Business Associate of the Covered Entity, and not a Business Associate of Pharmacy; (b) the Covered Entity has entered into a Business Associate Agreement with the 340B Program Administrator requiring the 340B Administrator to comply with HIPAA rules concerning the confidentiality, privacy, and security of Protected Health Information; (c) the volume and scope of Protected Health Information sought from Pharmacy under

this Agreement is the minimum necessary for the purposes contemplated herein; and (d) the Covered Entity and the 340B Program Administrator shall only use or disclose any Protected Health Information received in connection with this Agreement for the purposes contemplated herein.

Pharmacy certifies any pharmacists providing services under this Agreement shall be paid no less than the San Mateo Living Wage.

- 11. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of California.
- 12. Advertisement. Pharmacy reserves its rights in and control of the words "340B Direct Program," all of its symbols, trademarks, trade names, service marks and other such proprietary symbols and words presently existing or hereafter acquired, and all symbols related thereto or used in connection therewith. Covered Entity will not use such words, symbols, trademarks, trade names or service marks without the prior written consent of Pharmacy, which consent is hereby granted, for the limited purpose of communicating Pharmacy's participation under this Agreement to applicable Covered Entity Patients.
- 13. Entire Agreement. This Agreement, including all Exhibits and Schedules, amends, supersedes, and replaces the Original Agreement(s) in its entirety and constitutes the entire understanding between the Parties as to their respective obligations and, unless otherwise specified herein, may not be amended except by a writing signed by both Parties. The following exhibits and attachments are attached to this Agreement and incorporated into this Agreement by this reference:

Exhibit A - Covered Entity Reimbursement and Payment Terms All Claims Model Exhibit B - Funds Transfer Authorization Remit 340B Funds Directly to Covered Entity

Exhibit C - Covered Entity Sites

Exhibit D - List of Contracted Pharmacy Location(s)

Exhibit E - Corporate Compliance SMMC Code of Conduct

- **14. Third Party Beneficiaries.** The Parties specifically agree that Covered Entity Patients shall not be third party beneficiaries to this Agreement.
- 15. Waiver & Severability. Any failure by either Party to enforce or require the performance by the other Party of any of the terms or conditions of this Agreement shall not be constituted as a waiver of rights with respect to any subsequent breach of any term or condition of this Agreement. Any invalidity, illegality or unenforceability of any provision of this Agreement shall not invalidate or render illegal or unenforceable the remaining provisions hereof.
- **Survival.** Any term of this Agreement which by its nature extends beyond the termination hereof shall survive, including but not limited to obligations to pay amounts due hereunder,

indemnities, confidentiality obligations, audit provisions, limitations of liability, and disclaimers.

- 17. Assignment. Neither this Agreement nor any of the obligations to be performed hereunder may be assigned, directly or indirectly, by either Party without the prior written consent of the other Party; provided, however, that the preceding restriction shall not apply to the assignment by Pharmacy to an affiliated company or any successor entity through a sale, merger or other similar transaction. Any assignment or attempted assignment in violation of this restriction shall be void. In the event of any such permitted assignment, the obligations set forth herein shall be binding upon the succeeding entity.
- 18. Force Majeure. Neither Party shall be liable in any manner for any delay or failure to perform its obligations hereunder which are beyond such Party's reasonable control including, without limitation, delay or failure due to strikes, labor disputes, riots, earthquakes, extreme weather, fires, explosions, embargoes, war or other outbreak of hostilities, acts of terrorism, plague or disease, delay of carriers, suppliers or telecommunications providers, or government acts or regulations. If the period of non-performance exceeds sixty (60) days, the unaffected Party shall have the right to terminate this Agreement by thirty (30) days written notice to the affected Party, without liability except to pay for services rendered.
- **19. Taxes.** Each Party shall be responsible for its own State, Federal and local tax obligations resulting from revenue earned or otherwise related to services performed under this Agreement.
- 20. Independent Contractor. This Agreement shall not be construed nor deemed to create an employer/employee, principal/agent, or any relationship between Covered Entity and Pharmacy other than that of independent entities contracting with each other solely for the purpose of carrying out the terms and conditions of this Agreement. Pharmacy shall be solely responsible for its acts and omissions with respect to Pharmacy Services. Pharmacy agrees to render Pharmacy Services in accordance with professional standards applicable to Pharmacy Services and in accordance with rules and regulations of the applicable State Board of Pharmacy. Pharmacy shall have the right to refuse to serve any Covered Entity Patient where such service would violate any statute, regulation, or professional standard applicable to Pharmacy Services.
- 21. Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed to be an original as against any Party whose signature and/or initials appear thereon, and all of which shall together constitute one and the same agreement. This Agreement shall become binding when one or more counterparts hereof, individually or taken together, shall bear the signatures of all of the Parties.
- **22. Headings.** The headings of sections contained in this Agreement are for reference only and should not affect the meaning or interpretation of this Agreement.

- **23. Remedies.** The remedies specifically provided for herein are intended to be cumulative and shall not be deemed to exclude any other right or remedy that either Party may have at law or in equity.
- 24. Notice. Any notice required or given under this Agreement shall be provided in writing by one of the following methods: hand delivery, placing in the U.S. Postal Service, first class postage prepaid, facsimile transmission or email transmission, to the addresses and to the attention of the person specified below, or as modified at any time by either Party by written notice hereunder. The effective date of the notice shall be three (3) days after mailing as set forth above, upon receipt in the event of hand delivery, or upon confirmation of delivery if by facsimile or email transmission.

### Notice shall be sent to the following:

# **County of San Mateo**

222 W 39th Ave San Mateo, California 94403

ATTN: Director of Pharmacy Services, Victor Armendariz

Phone: <u>650-573-2366 / 650-573-2222</u>

Email: <u>varmendariz@smcgov.org</u>

Albertsons Companies, Inc. Audit related notices:

Albertsons Companies c/o 340BDirect PO Box 26574 Salt Lake City, UT 84126-0574

RE: 340B Audit Request

Email: ClientCare@340bdirect.com

All other notices:

250 East Parkcenter Blvd Boise, ID 83706 ATTN: Managed Health Care Contracting

With copy to:

250 East Parkcenter Blvd Boise, ID 83706 ATTN: Legal Department

<b>25.</b>	Contract Dollar Amount. In no event shall total payment for services under this
	Agreement exceed TEN MILLION DOLLARS, \$10,000,000.

In witness of and in agreement with this Agreement's terms, the parties, by their duly authorized representatives, affix their respective signatures:

For Contractor: Albertsons Companies, Inc.

DocuSigned by:				
Joe Last	11-30-2022   10:44:39	PST Lask, PharmD		
Contractor Signature		Contractor Name (please print)		

# COUNTY OF SAN MATEO

By:

President, Board of Supervisors, San Mateo County

Date:

ATTEST:

By:

Clerk of Said Board

#### Exhibit A

# Covered Entity Reimbursement and Payment Terms All Claims Model

1. <u>All Claims Model</u>. Subject to the terms of this Agreement and the eligibility rules determined by the Parties, Pharmacy will capture all Brand Drug and Generic Drug claims.

# 2. <u>Covered Entity Reimbursement.</u>

- **a.** Insured Claims. For each Insured Claim that is a Captured Claim, Pharmacy shall reimburse (or if applicable, charge) Covered Entity an amount equal to the Estimated Acquisition Cost (as defined below) minus the 340B Dispensing Fee calculated as follows (the "CE Reimbursement"):
  - i. Generic Drugs = \$11.00 + 10% of the EAC
  - ii. Brand Drugs = \$11.00 + 11% of the EAC
- **b.** Uninsured Claims. For each Uninsured Claim that is a Captured Claim, Pharmacy shall reimburse (or if applicable, charge) Covered Entity an amount equal to the amount paid by the Covered Entity Patient at the point of sale minus a 340B Dispensing Fee of \$18.00 (the "CE Reimbursement").
- 3. <u>Payment Terms</u>. For all Captured Claims for which Pharmacy has received payment from the applicable payer, Pharmacy shall remit amounts due to Covered Entity on a semi-monthly basis. Any amounts due by Covered Entity to Pharmacy shall be payable within thirty (30) days of receipt of an invoice.
- **4. <u>Definitions</u>**: For the purposes of this Agreement the following terms shall have the meanings set forth below:
  - a. "Estimated Acquisition Cost" or "EAC" shall be no greater than:
    - i. For Brand Drugs: WAC-4%
    - ii. For Generic Drugs:
      - 1. The NADAC Price; or
      - 2. If the NADAC Price is not available, SWP-70%
  - **b.** "NADAC Price" shall mean an estimated wholesale acquisition cost of the applicable drug (by NDC-11) in effect as of the date Pharmacy sold the drug to the Covered Entity Patient, based on the National Average Drug Acquisition Cost, as published by the Centers for Medicare & Medicaid Services.

- **c.** "SWP" shall mean Suggested Wholesale Price as published by First Databank (or similar published compendium of suggested wholesale price).
- **d.** "WAC" shall mean Wholesale Acquisition Cost as published by First Databank (or similar published compendium of suggested wholesale cost).
- **5.** Modification: Pharmacy, from time to time, with no less than thirty (30) days prior written notice to the Covered Entity, shall have the right to modify the CE Reimbursement terms and this **Exhibit A** to ensure that the CE Reimbursements are commercially reasonable in light of actual program performance and drug mix. At any time during the thirty (30) day period following notice of a change in the CE Reimbursements, the Covered Entity shall have the right to terminate the Agreement by written notice to Pharmacy.
- 6. Program Commencement. The actual commencement of the Pharmacy Services under this Agreement shall occur only upon mutual written agreement by both Parties. Either Party may, by written notice to the other, terminate this Agreement at any time prior to program commencement. Upon mutual written agreement of the Parties, the Pharmacy will process and capture 340B eligible claims up to a maximum of thirty (30) days prior to the actual program commencement date.

#### Exhibit B

# Funds Transfer Authorization Remit 340B Funds Directly to Covered Entity

Covered Entity hereby authorizes Pharmacy to remit funds directly to Covered Entity's bank account identified below. Pharmacy will remit funds only through Automated Clearing House (ACH) transfer at agreed upon payment schedules. Pharmacy shall have the right to offset against the remitted funds any amount owed to Pharmacy owed by Covered Entity including, but not limited to fees, charges or other monetary obligation arising out of this Agreement. Covered Entity is responsible for notifying Pharmacy thirty (30) days in advance of changes to transfer requirements. Covered Entity and Pharmacy agree to be bound by ACH association rules.

Covered Entity warrants the account is owned by Covered Entity and that the signer of this Funds Transfer Authorization is an authorized representative of Covered Entity with authority to determine where funds are transferred.

340B Program Administrator Name: **PharmaForce** 

BANKING INFORMATION	
Bank Name:	
Bank Street:	
Bank City:	Zip:
Bank Contact Name:	
Bank Contact Phone:	
Bank Contact Email:	
Bank Routing #:	
Bank Account #:	
Tax ID #:	
APPROVAL	
Covered Entity Name:	
CH091140; DSH050113; STD944039	9; TB944037
Authorized Signature:	
Printed Name:	
Title:	
	Email:

# Exhibit C \*Covered Entity Sites

CH091140; DSH050113; STD944039; TB944037 County of San Mateo 222 W 39th Ave San Mateo, California 94403

\* Covered Entity Sites means those individual Covered Entity locations related to Covered Entity, including all associated eligible child sites and/or grantees, that are listed on the HRSA.gov website pursuant to an executed enrollment or registration form which authorizes Covered Entity to contract with a licensed pharmacy to dispense 340B Drugs. Covered Entity locations shall only be eligible under this Agreement for so long as such locations are registered in the HRSA database and for which Covered Entity is the designated billing entity.

# Exhibit D List of Contracted Pharmacy Location(s)

Pharmacy Name	Store #	Future Store #	OPA Effective Date	DEA	NCPDP	Address	City	State	Zip
SAFEWAY PHARMACY #0305	0305		7/1/2013	BS3820861	0542173	1071 EL CAMINO REAL	REDWOOD CITY	CA	94063
SAFEWAY PHARMACY #0747	0747		7/1/2013	BS2962288	0545410	850 WOODSIDE ROAD	REDWOOD CITY	CA	94061
SAFEWAY PHARMACY #0970	0970		7/1/2013	BS0845074	0587090	1655 EL CAMINO REAL	SAN MATEO	CA	94402
SAFEWAY PHARMACY #2719	2719		7/1/2013	BS6678037	0553304	525 EL CAMINO REAL	MENLO PARK	CA	94025

### **Note:**

- 1) The Covered Entity or its agent will register or cause to be registered such unregistered contract pharmacies during the next available OPA registration period.
- 2) The Parties may terminate Contracted Pharmacy Locations under this Agreement only by mutual written agreement.

#### **EXHIBIT E**

# CORPORATE COMPLIANCE SMMC CODE OF CONDUCT (THIRD PARTIES)

Pharmacy recognizes and is fully dedicated to advancing San Mateo Medical Center's (SMMC) commitment to full compliance with all Federal, State, and other governmental health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements.

Pharmacy will comply with all Federal, State or other governmental health care program requirements.

Pharmacy, to the extent its contractual duties require it to submit the reports covered in this paragraph, will promptly submit accurate information for Federal health care cost reports including, but not limited to, the requirement to submit accurate information regarding acute available bed count for Disproportionate Share Hospital (DSH) payment.

Pharmacy will report to the SMMC Compliance Officer any suspected violation of any Federal health care program requirements within fifteen (15) days of discovery of the violation.

Pharmacy has the right to use the SMMC Disclosure Program by calling the Compliance Hotline at (800) 965-9775 or reporting incidents directly to the Compliance Officer. SMMC is committed to non-retaliation and will maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Pharmacy understands that non-compliance with Federal and State health care program requirements, and failing to report any such violations, could result in termination of the Agreement and/or any other penalties as permitted by law.

Pharmacy is responsible for acquiring sufficient knowledge to recognize potential compliance issues applicable to the duties outlined in the Agreement and for appropriately seeking advice regarding such issues.

Pharmacy will not offer, give, or accept any "kickback," bribe, payment, gift, or thing of value to any person or entity with whom SMMC has or is seeking any business or regulatory relationship in relation to said business or regulatory relationship (other than payments authorized by law under such relationships). Pharmacy will promptly report the offering or receipt of such gifts to the SMMC Compliance Officer.

Pharmacy will not engage in any financial, business, or other activity which may interfere or appear to interfere with the performance of the duties under the Agreement or that involve the use of SMMC/County property, facilities, or resources.

Pharmacy will cooperate fully and honestly in the event that SMMC and/or County is audited by an outside agency including, but not limited to, compliance audits regarding enforcement of Federal and State regulations, any applicable accreditation standards, and/or SMMC system-wide policies.

# TO REPORT VIOLATIONS, CALL THE COMPLIANCE HOT LINE: (800) 965-9775

Pharmacy, in executing this Agreement, certifies that an authorized representative has received this Code of Conduct, understands it, has authority to commit Pharmacy to this Code of Conduct, and has committed Pharmacy to comply with this Code of Conduct.