



WILL LIGHTBOURNE
DIRECTOR

State of California—Health and Human Services Agency
Department of Health Care Services



GAVIN NEWSOM
GOVERNOR

Date

Provider Name
Provider Address
Provider Address 2

RE: DEMAND FOR SELF-AUDIT OF 340B PROGRAM OVERPAYMENTS
AUDIT PERIOD: DECEMBER 1, 2016 THROUGH DECEMBER 31, 2019
PROVIDER NAME:
PROVIDER DBA:
NATIONAL PROVIDER IDENTIFIER (NPI):

Dear Provider:

The 340B Drug Pricing Program is administered by the Health Resources and Services Administration (HRSA), and allows qualified healthcare providers, known as covered entities, to purchase outpatient drugs from manufacturers at a substantial discount. To participate in the 340B Program, covered entities must register, enroll and comply with all program requirements, including the requirement to contract with the state to dispense 340B drugs. Participating covered entities may contract with pharmacies to dispense drugs purchased through the program on their behalf. As with covered entities, federal and state requirements related to the 340B Program likewise apply to contract pharmacies. The HRSA website provides a complete list of all covered entities that participate in the 340B Program and their contract pharmacies.

Welfare and Institutions Code section 14105.46 requires covered entities to dispense 340B outpatient drugs to Medi-Cal patients, when available. If the covered entity is unable to purchase a specific 340B drug, the covered entity may dispense a drug purchased at regular drug wholesale rates to a Medi-Cal patient, but is required to maintain documentation of the inability to obtain the 340B drug. Covered entities are required to submit claims to Medi-Cal for 340B drugs at rates not exceeding actual acquisition cost (AAC), plus a professional or dispensing fee. The statute also requires a covered entity to identify a 340B drug on the claim.

The Affordable Care Act, section 6402(a), established Social Security Act (the Act) section 1128J(d) [42 U.S.C. 1320 a-7k], which requires the reporting and returning of self-identified overpayments. Section 1128J(d)(1) of the Act requires a person who has received an overpayment to report and return the overpayment to the Secretary, the

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state, an intermediary, a carrier, or a contractor, as appropriate, at the correct address, and to notify the Secretary, state, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment. Additionally, section 1128J(d)(2) of the Act requires that an overpayment be reported and returned by the later of:

- (A) The date which is 60 days after the date on which the overpayment was identified;
- (B) The date any corresponding cost report is due, if applicable.

The Department of Health Care Services (Department) has determined that you are a **[contract pharmacy to a covered entity] OR [covered entity]** participating in the 340B Program. A contract pharmacy is a retail pharmacy dispensing 340B drugs on behalf of a covered entity, based on a contract between the covered entity and the pharmacy. The Department's review of your paid claims data for the audit period of December 1, 2016, through December 31, 2019, indicates that you may have received an overpayment by billing Medi-Cal for 340B outpatient drugs at rates in excess of your AAC, in violation of Welfare and Institutions Code section 14105.46. Further, you may have failed to identify 340B drugs on your claims during the audit period. The Department is entitled to recover all identified overpayments from Medi-Cal providers, pursuant to Title 22 of the California Code of Regulations, section 51458.1.

The Department directs you to perform a thorough self-audit for the audit period. Specifically, the Department directs you to do the following:

- 1) Identify and disclose all claims submitted to Medi-Cal for 340B drugs which you failed to flag as 340B drugs on the claim;
- 2) Identify and disclose all claims submitted to Medi-Cal for 340B drugs at rates exceeding your AAC;
- 3) Identify and disclose all drugs you were unable to purchase at 340B discounted rates, that you instead purchased at regular drug wholesale rates, and eventually dispensed to Medi-Cal patients; and
- 4) Identify and disclose all practitioners by name and NPI number who prescribed the 340B drugs which you furnished;
- 5) Identify and disclose all 340B drug wholesalers, including account number, from whom you purchased 340B drugs;
- 6) If you are a contract pharmacy, provide copies of all contracts you have with covered entities;
- 7) Calculate and disclose the total amount of any overpayment.

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As part of a self-audit, the Department directs you to complete and sign the summary form enclosed with this letter, which includes an attestation clause that your self-audit disclosures and the related self-audit summary on the form are true and accurate.

By **[INSERT DATE 60 DAYS FROM DATE OF LETTER]**, you must submit your completed self-audit findings and summary form to the following email address: **340B.Audit@dhcs.ca.gov**. By the same date, you must return all overpayments that you identified in your self-audit to the following mailing address:

Department of Health Care Services
Third Party Liability & Recovery Division
Overpayments Unit - MS 4720
P.O. Box 997425
Sacramento, CA 95889-7425

The Department's acceptance of an overpayment does not release you from being further audited by the Department, or from recovery of additional overpayments found to be due and owing. If you believe that returning an overpayment may impair your viability, you may contact the Department at the above email address to discuss alternative payment arrangements.

The Department will review your self-audit and summary form to determine whether additional information or documentation is necessary. If the Department determines that additional auditing is warranted, it may request additional records or conduct an on-site review of your facilities. You are instructed to retain all relevant documents and records for the audit period.¹ The Department will commence scheduling on-site reviews immediately following the relaxing of the state's travel and gathering restrictions due to the COVID-19 outbreak.

Questions regarding this self-disclosure should be directed to the above email address.

Sincerely,

Bruce Lim, CPA
Deputy Director

¹ Welfare and Institutions Code sections 14124.1, 14124.2, 14170.8, and Title 22 of the California Code of Regulations, sections 51476 and 51485 provide the Department with authority to review and request accurate books and records for services provided to Medi-Cal beneficiaries. Welfare and Institutions Code sections 14170, 14172, 14176, 14177 and Title 22 of the California Code of Regulations, sections 51458.1, 51470, 51488.1, authorize the Department to audit and recover overpayments made to providers.



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SELF-AUDIT SUMMARY

Instructions: In addition to the self-disclosures identified in the accompanying cover letter, you must complete this 340B Self-Audit Summary for each associated National Provider Identifier (NPI) you utilize to bill for 340B claims.

Please submit your self-disclosures and this document to 340B.Audit@dhcs.ca.gov on or before the due date indicated in the cover letter.

Name and Title of person completing the self-audit:

NPI:

Provider Legal Business Name:

Doing Business As:

Provider Address:

Provider Address 2:

Provider Contact Person and Title:

Email Address:

Phone Number:

340B ID:

I, [PRINT NAME] the undersigned, am [TITLE] with the above provider, and in that capacity, I am familiar with the information provided in this self-audit summary. I warrant and represent that the information I provide in this self-audit summary and the accompanying self-audit disclosures is true and accurate.

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Signature:

Date:

Pursuant to 42 U.S. Code section 1396r-8 and Welfare and Institutions Code section 14105, et seq., the provider must identify claims where Medi-Cal beneficiaries receive 340B purchased drugs, and consequently fill out claims correctly to prevent “duplicate discounts.” This occurs when the drug manufacturer gives the provider the discounted 340B price and pays a Medicaid rebate. In order to prevent the “duplicate discount”, providers must include the appropriate code on the claim. Physician Administered Drug claims require a “UD” modifier. Pharmacy claims need to have a “08” in the Basis of Cost Determination field. Both the “UD” modifier and the “08” inform DHCS that a 340B purchased drug was used for the claim. Our rebate system removes the claims from the drug manufacturers rebate invoice ensuring that the drug manufacturer is not subject to the “duplicate discount”.

1. Did the entity identify claims for which the Medi-Cal beneficiary received a 340B purchased drug?

If not, explain why not:

2. Were all Medi-Cal 340B claims billed at the discounted 340B price?

If not, explain why not:

3. Was a professional or dispensing fee charged for all claims?

If yes, how much was the fee?

If not, explain why not:

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4. After the self-audit, what is the total over payment amount identified?

5. Period related to the overpayment:

6. In the following table list all of the source documents used to determine the overpayment i.e. dispensing report, wholesale report, etc.:

Document List

7. Describe the procedures used to identify the overpayment:

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8. If you are a contract pharmacy, provide information below for each Covered Entity with which you contract (add additional pages as needed).

NPI:

Legal Business Name:

Doing Business As:

Covered Entity Contact Person and Title:

Email Address:

Phone:

340B contract period:

NPI:

Legal Business Name:

Doing Business As:

Covered Entity Contact Person and Title:

Email Address:

Phone:

340B contract period:

NPI:

Legal Business Name:

Doing Business As:

Covered Entity Contact Person and Title:

Email Address:

Phone:

340B contract period:

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Date

NPI:

Legal Business Name:

Doing Business As:

Covered Entity Contact Person and Title:

Email Address:

Phone:

340B contract period:

NPI:

Legal Business Name:

Doing Business As:

Covered Entity Contact Person and Title:

Email Address:

Phone:

340B contract period:

NPI:

Legal Business Name:

Doing Business As:

Covered Entity Contact Person and Title:

Email Address:

Phone:

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NPI:

Legal Business Name:

Doing Business As:

Covered Entity Contact Person and Title:

Email Address:

Phone:

340B contract period:

EXAMPLE