CA Department of Health Care Services
340B Self-Audit Request
Questions & Answers

General

Q1: What is DHCS' authority to request self-audits?

A1: DHCS' authority to request a self-audit falls under DHCS' general audit authority pursuant to Welfare & Institutions (W&I) Code Section 14170. In short, "Amounts paid for services provided to Medi-Cal beneficiaries shall be audited by the department in the manner and form prescribed by the department. The department shall maintain adequate controls to ensure responsibility and accountability for the expenditure of federal and state funds."

a. The self-audit approach is oftentimes utilized to offer auditees/providers the opportunity to satisfy program integrity (PI) expectations without the need for Audits & Investigations (A&I) to perform a field visit. In so doing, we can achieve our PI objectives with minimal disruption to the provider. Note, however, the audit may be expanded depending on the results of the self-audit. This is determined on a case- by-case basis.

b. The self-audit also falls under the spirit of the provider self-disclosure requirements of the Social Security Act (the Act) Section 1128J(d) [42 U.S.C. 1320 a-7k], established under the Affordable Care Act (ACA) Section 6402(a), which requires the reporting and returning of self-identified overpayments.

Q2: Have all 340B self-audit requests been sent? If not, is there a due date for sending these requests out?

A2: DHCS' self-audit requests are intended for all 340B covered entities and contract pharmacies that participate in the Medi-Cal program. There is no fixed period of time when this objective will be fully achieved. DHCS is mailing requests for self-audits in batches/phases, without a fixed period of time. DHCS currently does not have a time- frame when the next batch of request letters will be disseminated.

Q3: How does DHCS decide which covered entities and contract pharmacies to send the 340B self-audit requests to?

A3: DHCS compiled our list of impacted entities from those covered entities and contract pharmacies listed on the HRSA 340B website who participate in the Medi-Cal program.

Q4: Will all Covered Entities that receive the DHCS Letter fill out the same forms?

A4: Yes, all covered entities that receive our letter will initially be required to fill out the same form.

Q5: If the appropriate team within the entity has not received a letter, can they reach out to the 340B email address?

A5: Yes, entities are welcome to contact us at 340B.Audit@dhcs.ca.gov at any time to determine the status of their letter.

Q6: What if a provider needs more time to complete the self-audit by the stated deadline? Can a covered entity or contract pharmacy request a deadline extension?

A6: Yes, a provider may request an extension by submitting their request via email to 340B.Audit@dhcs.ca.gov. DHCS will consider additional deadline extension requests on a case-by-case basis. If the provider has a reasonable justification to support its request, DHCS will consider granting a reasonable extension. We understand these are challenging times, so we are committed to being as flexible as possible.

Q7: What if a provider did not purchase any 340B drugs? How should it respond to DHCS' self-audit request?

A7: If the covered entity, contract pharmacy, or any authorized agent acting on behalf of the covered entity or the contract pharmacy did not purchase or utilize any 340B drugs to bill Medi-Cal or provide services to any Medi-Cal beneficiary, please attest to this fact on the self-audit summary form that accompanies the letter and submit the completed form via email to 340B.Audit@dhcs.ca.gov.

Q8: How should a covered entity or contract pharmacy respond if no 340B drugs were billed to Medi-Cal during the self-audit period?

A8: See answer to Q7.

Self-Audit Scope

Q9: Does the self-audit only apply to 340B drugs billed to fee-for-service (FFS) Medi-Cal, including those carved out from Medi-Cal managed care?

A9: Yes, DHCS' request for 340B self-audits by 340B contract pharmacies and covered entities is restricted to Fee-For-Service (FFS) beneficiaries and Medi-Cal Managed Care Plan (MCP) beneficiaries utilizing carved-out drugs that were paid by FFS.

a. See attached All Plan Letter 16-004 that addresses MCP carved-out drugs.

Q10: Does this self-audit apply to both Medi-Cal FFS pharmacy and medical claims, such as physician administered drugs?

A10: Yes, the self-audit applies to both Medi-Cal FFS pharmacy and medical claims, including physician administered drugs.

Q11: Are providers expected to include FFS claims when Medi-Cal is not the primary payer, such as Medicare crossover claims, etc.?

A11: Yes, providers should ensure 340B claims are properly identified and billed. (W&I Code Section 14105.46)

Q12: Can the price and NDC most recently purchased under the 340B account be used as the basis for audit results?

A12: No, use the appropriate actual acquisition cost (AAC) as charged by the manufacturer for each claim line. Refer to W&I Code Section 14105.46.

Q13: Do the self-audits apply to specific NPI numbers or locations?

A13: No, the self-audit request applies to the legal entity rather than a specific location. It applies to all of a provider's 340B billing, whether billed directly by the covered entity, contracted pharmacy, or billed using any other method.

Q14: Is DHCS open to allowing providers to conduct the self-audit through a sampling methodology?

A14: Providers should conduct self-audits using methodologies that provide DHCS reasonable assurance that no overpayment occurred.

Q15: Is the 340B self-audit request intended to identify drugs that did not have a 340B price or those drugs that have a 340B price but the provider was unable to get 340B pricing due to manufacturer restrictions/contract issues?

A15: Regardless of the reason why a covered entity was unable to purchase 340B drugs, sufficient documentation should be available to explain what transpired and the efforts taken to ensure compliance with statutory requirements (e.g. W&I Code Section 14105.46).

Audit Criteria and Definitions

Q16: How does DHCS define a 340B overpayment?

A16: A 340B overpayment is any amount that exceeds the amount authorized by W&I Code Section 14105.46.

Q17: When calculating overpayment, do providers consider only the drug AAC or do providers also consider the administration fees associated with the claim?

A17: W&I Code Section 14105.46 (d): A covered entity shall bill an amount not to exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the United States Code plus the professional fee pursuant to Section 14105.45 or the dispensing fee pursuant to Section 14132.01.

Q18: What is the definition of "Professional Dispensing Fee"?

A18: This is defined in W&I Code Section 14105.45.

Q19: If there was an underpayment, how would providers address the underpayment appropriately?

A19: If there was an underpayment, the Claim Inquiry Form (CIF) should be submitted to the Fiscal Intermediary in a timely manner to request an adjustment. Please refer to the Medi- Cal Provider Billing Manuals for instructions on adjustment requests for underpayments.

Q20: Clarification on the unable to purchase would be helpful—is the request intended to identify drugs that didn't have a 340B price (e.g., manufacturers that don't participate in the program) or those drugs that have a 340B price but the covered entity was unable to get 340B pricing due to manufacturer restrictions/contract issues?

A20: Regardless of the reason why a covered entity was unable to purchase 340B drugs, sufficient documentation should be available to explain what transpired and the efforts taken to ensure compliance with statutory requirements (e.g. W&I Code Section 14105.46).

Q21: Would you please provide additional clarification regarding DHCS' specific requests summarized below and listed on page two of DHCS' request for self-audit letter?

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.**

A21: **Identify and disclose all claims submitted to Medi-Cal for 340B drugs which you failed to flag as 340B drugs on the claim.**

A covered entity shall identify a 340B drug on the claim submitted to the Medi-Cal program for reimbursement. (W&I Code Section 14105.46(e).)

In order to comply with federal law, claims must be filled out 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".

Identify and disclose all claims submitted to Medi-Cal for 340B drugs at rates exceeding your AAC.

All claims submitted to Medi-Cal for 340B drugs must comply with W&I Code Section 14105.46(d):

A covered entity shall bill an amount not to exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the United States Code plus the professional fee pursuant to Section 14105.45 or the dispensing fee pursuant to Section 14132.01.

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.

If a 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 beneficiary. If a covered entity dispenses a drug purchased at regular drug wholesale rates pursuant to this subdivision, the covered entity is required to maintain documentation of their inability to obtain the 340B drug. (W&I Code 14105.46(c).) For the purpose of the self-audit, providers should summarize the reasons and retain the detailed records.

Identify and disclose all practitioners by name and NPI number who prescribed the 340B drugs which you furnished.

The contract pharmacy should work with the covered entities to compile the information related to practitioners. If not, the pharmacy should state why the information cannot be obtained.

Identify and disclose all 340B drug wholesalers, including account number, from whom you purchased 340B drugs.

Every primary supplier of pharmaceuticals is required to provide documentation necessary for DHCS to perform its auditing functions. (W&I Code Sections 14107, 14170.8, 14124.1, 14124.2; 22 CCR Section 51476.)

If you are a contract pharmacy, provide copies of all contracts you have with covered entities.

W&I Code Sections14170, 14170.8, 14124.1, 14124.2 and 22 CCR Section 51476 require the submission of requested documents which include all contracts with covered entities.

Calculate and disclose the total amount of any overpayment.

An overpayment is billing an amount that exceeds "the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the United States Code plus the professional fee pursuant to Section 14105.45 or the dispensing fee pursuant to Section 14132.01." (W&I Code Section 14105.46(d).)

Release 2 Updated Questions (11/30/21):

Q22: Recent self-audit requests letters (August 31, 2021) reflect an audit time period of "12/1/2016 through Current." What is "Current"?

A22: "Current" is up to the issuance of the audit letter on August 31, 2021.

Q23: Are providers required to identify and disclose overpayments beyond the audit period?

A23: Yes, DHCS expects the provider to (1) update its practices and procedures immediately to ensure further overpayments cease, and (2) report total overpayments that materialized from the flawed practices regardless of time period.

The expectation to report all overpayments regardless of time period based upon the requirements and spirit of 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.

Q24: Why was the audit period updated from [12/1/16 through 12/31/19] to [12/1/16 through Current]?

A24: The audit period was updated because a number of providers that received our previous request assumed that overpayments related to periods beyond the original audit period of 12/1/16 through 12/31/19 are not required to be disclosed. This is an inaccurate assumption.

Release 3 Updated Questions (11/27/23):

PHYSICIAN ADMINISTERED DRUGS

Q1: Which authorities are applicable for reimbursement of outpatient hospitals, free-standing clinics, and physicians for Physician Administered Drugs (PAD claims)?

A1: Hospitals, free-standing clinics, and physicians receive reimbursement for defined **injections** and **immunizations** through W&I § 14105.456 & CCR Title 22 § 51503(e) and if applicable, **blood factors** through W&I § 10105.86.

Q2: Which authorities are applicable for reimbursement of outpatient community clinics, free clinics, and intermittent clinics for Physician Administered Drugs?

A2: Non-pharmacy providers receive reimbursement for defined **injections** and **immunizations** through W&I § 14105.456 & CCR Title 22 § 51503(e) and **blood factor** through W&I § 10105.86.

Q3: **Which authorities are applicable for reimbursement of outpatient community clinics, free clinics, and intermittent clinics enrolled in Family Planning, Access, Care, and Treatment (FPACT) for Physician Administered Drugs?**

A3: Community clinic, free clinics, and intermittent clinics enrolled in FPACT program that allow an **Administration Fee** and **Clinic Dispensing Fee** billing through the Family PACT program is defined in W&I § 14132.01.

Q4: If a hospital claim is submitted for Physician Administered Drugs dispensed by an unenrolled pharmacy, is it eligible for the "Pharmacy" Professional Dispensing Fee?

A4: No, it is billing a PAD Claim, it is not entitled to the "**Pharmacy" Professional Dispensing Fee**.

Pharmacy

Q 5: Which dispensing fee is allowed for an enrolled outpatient pharmacy provider to bill?

A 5: A pharmacy is allowed the "**Pharmacy" Professional Dispensing Fee** pursuant to W&I § 14105.45 (the legislative authority which defines the current "**Pharmacy" Professional Dispensing Fee** of $10.05 or $13.20) and is for a provider that meets the definition of a pharmacy provider type and is enrolled in Medi-Cal as an outpatient pharmacy provider.

Q6: What is required for a Hospital's on campus pharmacy to bill "Pharmacy" Professional Dispensing Fee?

A6: A pharmacy needs to be licensed, enrolled in Medi-Cal as an outpatient pharmacy provider and billing the appropriate (pharmacy) claim. In order to receive a **"Pharmacy" Professional Dispensing Fee** as defined in W&I § 14105.45 The Medi-Cal pharmacy reimbursement methodology is comprised of two components; the drug ingredient cost and the "**Pharmacy" Professional Dispensing Fee**. This dispensing fee is only reimbursed to Medi-Cal enrolled

outpatient pharmacies for claims related to the dispensing of a covered outpatient drug. Under existing federal Medicaid authority (SSA, Section 1927), the term "covered outpatient drug" does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this title as part of payment for the following and not as direct reimbursement for the drug):

(A) Inpatient hospital services.
(B) Hospice services.
(C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.
(D) Physicians' services.
(E) Outpatient hospital services.

(F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded.
(G) Other laboratory and x-ray services.
(H) Renal dialysis.