

September 20, 2023

**VIA Electronic Mail to:** [Daniel.Tsai@cms.hhs.gov](mailto:Daniel.Tsai@cms.hhs.gov)

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Deputy Administrator and Director  
Center for Medicaid and CHIP Services  
Centers for Medicare & Medicaid Services  
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Baltimore, MD 21244

**RE: State Medicaid Plan Non-Recognition of Proprietary Laboratory Analysis (PLA) Codes**

Dear Mr. Tsai:

On behalf of the undersigned organizations, and in follow-up to our previous meetings and correspondence with CMS regarding the above-captioned issue, I am reiterating our request for CMS to issue a written communication to the states (e.g., “State Medicaid Director Letter” or other appropriate communication) that instructs State Medicaid programs to recognize and process claims submitted with Proprietary Laboratory Analysis (“PLA”) codes established by the American Medical Association’s *Current Procedural Terminology* (“CPT”) Editorial Panel.

PLA codes are CPT codes that describe proprietary clinical laboratory analyses provided either by a single (sole source) laboratory or licensed or marketed to multiple providing laboratories (e.g., cleared or approved by the U.S. Food and Drug Administration). Tests described by PLA codes include EUA-authorized tests for SARS-Cov-2, FDA-approved companion diagnostics for advanced cancer therapies, and other novel, innovative tests. Individual states’ continued refusal to recognize PLA codes unnecessarily restricts Medicaid beneficiaries’ access to the tests described by these codes and is not consistent with existing law.

Under the regulations implementing the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (collectively, “HIPAA”), covered entities that transmit any health information in electronic form – including “health plans” – must use the applicable designated medical data code set that is valid at the time health care is furnished.<sup>1</sup> HIPAA regulations explicitly identify State Medicaid programs as “health plans.”<sup>2</sup> Therefore, State Medicaid programs must process claims using the applicable “designated code set.” The designated code set for clinical laboratory tests is the combination of CPT and the Healthcare Common Procedure Coding System (HCPCS).<sup>3</sup> The CPT codebook lists PLA codes in Appendix O, and explicitly notes that such codes are also included “at the end of the Pathology and Laboratory section of the CPT code set.”<sup>4</sup> Therefore, PLA codes are part of the “designated code set” for clinical laboratory tests, and State Medicaid plans must recognize and process claims that include such codes under HIPAA.

In our previous communications, CMS indicated that it understood and agreed with the foregoing analysis, and we understand the agency has repeatedly delivered this message orally to the states. **Notwithstanding CMS’s instructions, states continue to refuse to accept PLA codes.** In the following table (as supported by attachments), we provide examples where state Medicaid agencies recently

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<sup>1</sup> 45 C.F.R. § 162.1000(a).

<sup>2</sup> *Id.* § 160.103.

<sup>3</sup> *Id.* §§ 162.1002(c)(1), 162.1002(a)(5)(iv).

<sup>4</sup> See American Medical Association, CPT 2023, Appendix O.

indicated that they would not process claims submitted with PLA codes, and that laboratories should instead file such claims with less-specific Category I CPT codes:

State	Explicit feedback describing non-acceptance of PLA codes
Connecticut	<i>“After review, the Department has chosen to maintain the current policy and <b>not add individual PLA codes for coverage under CMAP. CMAP’s established policy has been for providers to bill with a comparable existing Category I CPT lab code or request PA under an unlisted code.</b>”</i>
Georgia	<i>“Do not open coverage for 0242U, 0326U or 0334U. <b>Instead, ask the provider to report 0242U and 0326U using code 81479. Report 0334U using code 81455.</b></i> <ul style="list-style-type: none"> <li><i>• 0242U and 0326U use 81479. Rationale: 0242U and 0326U are cell-free DNA analysis. There is not a corresponding CPT code that describes cell-free DNA analysis. Medicaid pays \$890.60 for 81479. Medicare does not have a price for 0326U.</i></li> <li><i>•0334U use 81455. Rationale: 81455 is DNA analysis of tumor tissue 51+ genes, and 0334U is DNA analysis of tumor tissue, 84+ genes. Same type of analysis. The fee for both codes is same, \$2919.60.”</i></li> </ul>
Michigan	<i>“Michigan Medicaid typically does not cover laboratory specific PLA procedure codes with a few exceptions. <b>Providers are encourage[d] to report covered services using category 1 CPTs when billing Medicaid for services.</b> Providers are referred to the current edition of the CPT and HCPCS manuals published by the American Medical Association (AMA) for selection of the procedure code that accurately represents the service or item rendered.”</i>

Telling a laboratory that the state will not accept a PLA code for the specific – and only – test that the PLA code describes is a refusal to recognize the code itself, in violation of the state’s obligations under HIPAA. Furthermore, instructing a lab to use a less specific CPT code or non-specific unlisted code instead of the most specific code for the test contradicts the instructions set forth the NCCI Policy Manual for Medicaid.<sup>5</sup>

As of June 2023, fifteen (AL, CO, FL, ID, IL, MA, MS, NV, NY, PA, RI, SC, TX, VT, WV) state Medicaid programs do not list any PLA codes on their clinical laboratory fee schedules. As illustrated below, certain states appear to have decided to exclude these codes from fee schedules based solely on their status as PLA codes, without any consideration of the evidence supporting any specific test:

State	Explicit feedback describing non-acceptance of PLA codes
Idaho	<i>“<b>Services represented by Proprietary Laboratory Analyses (PLA) codes do not usually meet the requirement of medical necessity for standard of care or are considered experimental/investigational.</b> PLA codes are for used for laboratory tests provided by a single source or licensed to other laboratories for processing. Unless specifically stated in the CPT® manual PLA codes do not meet the</i>

<sup>5</sup> See Medicaid National Correct Coding Initiative Policy Manual, Chapter X, at X-3, <https://www.cms.gov/files/document/medicaid-ncci-policy-manual-2023-chapter-10.pdf> (last visited June 2, 2023) (stating that laboratories “shall report the Healthcare Common Procedure Coding System/Current Procedural Terminology (HCPCS/CPT) code that describes the procedure performed to the greatest specificity possible”); see also Chapter I, at I-26, <https://www.cms.gov/files/document/medicaid-ncci-policy-manual-2023-chapter-1.pdf> (“If a [laboratory] provides a service that is not accurately described by other HCPCS/CPT codes, the service shall be reported using an unlisted procedure code.”).

State	Explicit feedback describing non-acceptance of PLA codes
	<i>standards for Category I codes. They are only required to be commercially available in the United States for use on human specimens and be requested by the laboratory or manufacturer. Laboratory tests represented by a PLA that do not meet the requirements to be a Category I CPT code are not covered and cannot be billed with an unspecified code.</i>

While we acknowledge that states maintain the right to determine whether individual services are medically necessary, it is facially unreasonable for states to maintain across-the-board policies of non-coverage for PLA codes on the grounds that such assays are investigational, particularly when several PLA codes are used to report FDA-approved companion diagnostics, EUA-authorized COVID tests, and other standard of care assays. Rather, such “coverage” policies appear to reflect the state’s refusal to recognize the PLA code set itself, in violation of the state’s obligations under HIPAA.

Finally, we note that six additional states (CT, NC, ND, NH, SD, WI) only include those PLA codes associated with COVID-19 testing on their fee schedules. For your reference, we have included a link to all twenty-one state laboratory fee schedules referenced above – please see the Appendix for more information.

If you would prefer that any of the above information be submitted via a more formal channel, please let us know – we would be happy to provide additional information via the CMS Administrative Simplification Enforcement and Testing Tool (ASETT) portal to facilitate an official inquiry.

**Given these states’ refusal to recognize the PLA code set, we encourage CMS to issue a written communication to the states (e.g., “State Medicaid Director Letter” or other appropriate communication) that explicitly reiterates State Medicaid programs’ obligation to timely recognize and process claims that include PLA codes.** In pertinent part, such language could read:

*As “covered entities” under the Health Insurance Portability and Accountability Act of 1996 (as amended by the Health Information Technology for Economic and Clinical Health Act), State Medicaid programs must process claims using the applicable “designated code set.” Proprietary Laboratory Analysis (PLA) codes are part of the “designated code set” for clinical laboratory tests. Therefore, CMS reminds State Medicaid plans that they must recognize and process claims that include PLA codes and shall not instruct laboratories to use alternative code(s) when a PLA code is the most appropriate, specific code to report the test performed.*

**Furthermore, we are requesting a teleconference to walk through these updates, and to answer any questions you may have.** We would be pleased to meet at your convenience.

Thank you in advance for your attention to this correspondence. If you have any questions, please contact Michael Ryan at 202.756.8088, or via e-mail at [mryan@mwe.com](mailto:mryan@mwe.com).

Sincerely,

AdvaMedDx  
 American Clinical Laboratory Association  
 American Medical Association  
 American Society for Clinical Pathology  
 Association for Molecular Pathology

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Coalition for 21<sup>st</sup> Century Medicine  
College of American Pathologists  
Point of Care Testing Association

CC: Jonathan Blum, Principal Deputy Administrator & Chief Operating Officer  
Anne Marie Costello, Deputy Director, CMCS  
Sara Vitolo, Deputy Director, CMCS  
Jackie Glaze, Deputy Director, Medicaid & CHIP Operations Group  
Barbara Richards, Deputy Director, Medicaid & CHIP Operations Group  
Ed Dolly, Director, Division of State Systems

**Appendix: Link to State Medicaid Fee Schedules**

States that do not have any PLA codes on their fee schedules

State	Link to fee schedule
AL	<a href="#">7.3G_Lab_Radiology_Fee_Schedule_3-28-23.pdf (alabama.gov)</a>
CO	<a href="#">01_CO_Fee_Schedule_Health_First_Colorado_01012023_V2.1.pdf</a>
FL	<a href="#">Independent Lab Fee Schedule 2023.pdf (myflorida.com)</a>
ID	<a href="#">April to June 2023 Fee Schedule - PDF (idaho.gov)</a>
IL	<a href="#">03152023PractitionerFeeScheduleEffective01012023Final.pdf (illinois.gov)</a>
MA	<a href="#">114.3 CMR 20.00: CLINICAL LABORATORY SERVICES (mass.gov)</a>
MS	<a href="https://medicaid.ms.gov/providers/fee-schedules-and-rates/#">https://medicaid.ms.gov/providers/fee-schedules-and-rates/#</a> (click “Pathology Laboratory”)
NV	<a href="#">FeeSchedules (nv.gov)</a> (click “Provider Type 43”)
NY	<a href="#">Provider Manuals - Laboratory (emedny.org)</a>
PA	<a href="https://www.humanservices.state.pa.us/OUTPATIENTFEESCHEDULE/Search/Submit">https://www.humanservices.state.pa.us/OUTPATIENTFEESCHEDULE/Search/Submit</a> (select “28 - Laboratory” from drop-down menu)
RI	<a href="#">outpatient lab october 2022.pdf (ri.gov)</a>
SC	<a href="#">Fee Schedules   SC DHHS</a> (click “Independent Lab and Radiology Fee Schedule”)
TX	<a href="#">FeeSchedules (tmhp.com)</a> (click “Laboratory Independent”)
VT	<a href="#">Vermont Medicaid Portal (vtmedicaid.com)</a>
WV	<a href="#">2023 Clinical Lab Fee Schedule eff 4.1.23-3.31.24.pdf (wv.gov)</a>

States that only have COVID-related PLA codes on their current fee schedules

State	Link to fee schedule
CT	<a href="https://www.ctdssmap.com/ctportal/provider/provider-fee-schedule-download">https://www.ctdssmap.com/ctportal/provider/provider-fee-schedule-download</a> (click “Lab”)
NC	<a href="https://medicaid.ncdhhs.gov/laboratory-fee-schedules-sept-19-2022-pdf/open">https://medicaid.ncdhhs.gov/laboratory-fee-schedules-sept-19-2022-pdf/open</a>
ND	<a href="#">2022-7-1 Professional Fee Schedule.xlsx (nd.gov)</a>
NH	<a href="#">ADH-REF-101 (nh.gov)</a>
SD	<a href="#">Lab_Services_latest.pdf (sd.gov)</a>
WI	<a href="#">Max Fee Download (wi.gov)</a> (click “Medical – Laboratory”)