

July 16, 2021

VIA Electronic Mail to: Daniel.Tsai@cms.hhs.gov

Daniel Tsai
Deputy Administrator and Director
Center for Medicaid and CHIP Services
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

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

Dear Mr. Tsai:

On behalf of the undersigned organizations, I am asking CMS to issue a “State Medicaid Director Letter” 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 and can be 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).

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.¹ HIPAA regulations explicitly identify State Medicaid programs as “health plans.”² 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).³ 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.”⁴ 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.

The CPT Editorial Panel created the first PLA codes more than four years ago (in 2017). However, many state Medicaid programs still outright refuse to process claims that include PLA codes, or experience meaningful delays in their recognition of newly-created codes, notwithstanding their obligation to do so under HIPAA.

We recognize that updating claims processing systems to recognize these codes takes time, and note that certain jurisdictions have only recently done so.⁵ We further understand and acknowledge that State Medicaid programs’ decision whether to recognize PLA codes is separate from the decision whether to

¹ 45 C.F.R. § 162.1000(a).

² *Id.* § 160.103.

³ *Id.* §§ 162.1002(c)(1), 162.1002(a)(5)(iv).

⁴ See American Medical Association, CPT 2021, Appendix O, at 936-937.

⁵ Medi-Cal completed its implementation of the PLA codes on January 25, 2021. See California Dep’t of Health Care Services, Proprietary Laboratory Analyses (PLA) Codes Now Implemented (Jan. 29, 2021), https://files.medi-cal.ca.gov/pubsdoco/newsroom/newsroom_27885_02.aspx.

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cover claims submitted with PLA codes (based on the program's assessment of the underlying test and the medical necessity of such test for the management of individual Medicaid beneficiaries). However, given the ongoing delay in recognition of the PLA code set, we encourage CMS to issue a "State Medicaid Director Letter" that clarifies State Medicaid programs' obligation to timely recognize and process claims that include PLA codes.

Thank you in advance for your attention to this correspondence. If you have any questions, please contact Paul Radensky at 202.756.8794, or via e-mail at pradensky@mwe.com.

Sincerely,

American Medical Association (AMA)
American Clinical Laboratory Association (ACLA)
American Association for Clinical Chemistry (AACC)
AdvaMedDx
American Society for Clinical Pathology (ASCP)
Association for Molecular Pathology (AMP)
Coalition for 21st Century Medicine
Point of Care Testing Association (POCTA)
Physician Fee Schedule Pathology Payment Coalition