FEDERAL MEDICAID NOTICE AND PUBLIC HEARING NOTICE
OHIO DEPARTMENT OF MEDICAID

DATE: December 21, 2015
TIME: 1:00 p.m.
LOCATION: Room A501, Lazarus Government Center
50 West Town Street, Columbus, OH 43215

Pursuant to section 5164.02 and Chapter 119. of the Ohio Revised Code and 42 CFR 447.205, the director of the Ohio Department of Medicaid gives notice of the Department's intent to consider the amendment, rescission, or adoption of the rules identified below and to hold a public hearing on these rules.

In accordance with provisions set forth in section 119.032 of the Ohio Revised Code, a systematic review has been made of the nine existing rules in Chapter 5160-11 of the Ohio Administrative Code:

5160-11-01, "Definitions: independent laboratory, portable X-ray supplier, independent diagnostic testing facility (IDTF), and mammography supplier"
5160-11-02, "Provider requirements: independent laboratory, portable X-ray supplier, independent diagnostic testing facility (IDTF), mammography supplier, and other providers of laboratory services"
5160-11-03, "Laboratory services: coverage and limitations"
5160-11-04, "Laboratory: exceptions for FQHCs, RHCs, OHFs, and hospital outpatients"
5160-11-05, "Laboratory specimens sent to the Ohio Department of Health (ODH) state laboratories"
5160-11-06, "Portable X-ray suppliers: covered services and limitations"
5160-11-07, "Independent diagnostic testing facility: coverage and limitations"
5160-11-08, "Reimbursement for laboratory, portable X-ray supplier, and independent diagnostic testing facilities"
5160-11-10, "Radiology procedures that are subject to the Clinical Laboratory Improvement Amendments (CLIA) requirements"

These rules are being rescinded and replaced with six new rules:

5160-11-01, "Laboratory-related services: definitions and explanations"
5160-11-02, "Laboratory-related services: general provisions"
5160-11-03.1, "Laboratory-related services: provisions specific to laboratory procedures"
5160-11-03.2, "Laboratory-related services: provisions specific to portable X-ray services"
5160-11-03.3, "Laboratory-related services: provisions specific to independent diagnostic testing facility (IDTF) services"
5160-11-09, "Laboratory-related services: claim payment"

Most of the changes involve improvements in organization of the chapter, structure of the individual rules, and clarity of phrasing. A few specific revisions are worth noting:

- The phrase "laboratory-related services" is introduced as a collective term encompassing clinical diagnostic laboratory procedures, physician pathology procedures and other professional laboratory services, nonroutine specimen collection, neonatal diagnostic screening performed with a prefabricated kit, diagnostic radiology services, and other

diagnostic procedures (e.g., MRI, ultrasound, imaging-guided placement of catheters or administration of contrast media, electrocardiography, stress tests, sleep studies).

- In keeping with recent advances in technology and policies adopted by the Centers for Medicare and Medicaid Services (CMS), the phrase "dated and signed by the physician" has been removed from the description of a written order because it could be misinterpreted to require handwriting. Many forms are now signed and dated electronically.
- For purposes of payment coordination and program integrity, a provision is added that explicitly requires a portable X-ray supplier to be enrolled in Medicare as a supplier of portable X-ray services.
- Under the existing rules, a written order for a portable X-ray service or for a procedure performed by an independent diagnostic testing facility (IDTF) must include a rationale for the service or procedure. The new rules instead require that at least one appropriate diagnosis code be included on all written orders, because a diagnosis code is generally easier to provide than a narrative and imparts just as much information.
- The existing rules specify that laboratory providers may submit claims only for those clinical diagnostic laboratory procedures they actually perform, but an exception is made for federally-qualified health centers (FQHCs), rural health clinics (RHCs), and outpatient health facilities (OHFs) that meet certain conditions. The new rules extend this exception to a hospital acting as a reference laboratory provider when the referring laboratory provider is wholly owned by the reference laboratory provider, the reference laboratory provider is wholly owned by the referring laboratory provider, or both of them are wholly owned by a third entity.
- The taking of a urine sample by catheterization is excluded from the handful of specimen collection procedures that are treated as laboratory-related services. Catheterization is really a physician service, and almost no laboratory providers submit claims for this procedure.
- The new rules prescribe a method by which maximum payment amounts are established for laboratory-related services that are payable under the Medicare physician fee schedule or under the clinical laboratory fee schedule published by CMS. A list of Medicaid maximum payment amounts and additional claim-related information for these procedures will be available through the department's web page. Accordingly, entries for these procedures will be removed from the main Medicaid non-institutional payment schedule (which is published as Appendix DD to rule 5160-1-60 of the Ohio Administrative Code).

It is estimated that the changes to these rules will have no effect on annual aggregate Medicaid expenditures.

The public hearing will be held at the date, time, and location listed at the top of this notice. Both written and oral testimony will be accepted at the public hearing, and written comments submitted or postmarked no later than the date of the public hearing will be treated as testimony.

Any person affected by these rules may examine them and obtain a copy, without charge, at the following locations:

Ohio Department of Medicaid, 50 West Town Street, Fourth Floor, Columbus, Ohio 43215;
Any county department of job and family services; or
On the internet at http://www.registerofohio.state.oh.us/.

Testimony on the proposed rules may also be reviewed at the Ohio Department of Medicaid, 50 West Town Street, Fourth Floor, Columbus, Ohio 43215.

Requests for a copy of the proposed rules or a copy of testimony on the rules should be submitted in any of the following ways:

By mail to the Rule Administrator, Office of Chief Legal Counsel, Ohio Department of Medicaid, 50 West Town Street, Fourth Floor, Columbus, OH 43215;
By fax to (614) 752-3986; or
By e-mail to rules@medicaid.ohio.gov.