5101:3-11-01 Independent laboratory, x-ray supplier, and independent diagnostic testing facility: definitions.

(A) Independent laboratory.

"Independent laboratory" means a facility for the biological, microbiological, immunological, immunohematological, serological, chemical, hematological, cytological, pathological or other examination of materials of the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment, or for the assessment of an individual's health. An "independent laboratory" is a facility which that is independent of the attending or consulting physician's office, a clinic, an ambulatory surgery center, or a hospital. A laboratory under the ownership and direction of a physician or physician group, such as a pathologist(s), is considered an independent laboratory if the physician holds himself or herself and the facilities of his or her office out to other physicians as being available for the performance of laboratory procedures. Facilities only collecting or preparing specimens or only serving as a mailing service and not performing testing are not considered laboratories.

(B) Independent portable x-ray supplier.

"Independent portable x-ray supplier" means an entity for the performance of diagnostic x-ray procedures when the services are provided in a patient's place of residence.

(C) Independent diagnostic testing facility.

- (1) "Independent diagnostic testing facility" means a facility for the performance of diagnostic tests which that are performed by licensed or certified nonphysician personnel under appropriate physician supervision. The facility may be a fixed location, a mobile entity, or an individual nonphysician practitioner, and in all cases must comply with applicable state law. The "independent diagnostic testing facility" must meet all standards and provide services in accordance with 42 C.F.R. 410.33 (October 1, 2005). An "independent diagnostic testing facility" is a facility which that is independent of the attending or consulting physician's office or group practice, a clinic, an ambulatory surgery center or a hospital. An independent diagnostic testing facility under the ownership and direction of a physician is considered an independent diagnostic testing facility if the physician holds himself or herself and the facilities of his or her office out to other physicians as being available for the performance of diagnostic tests.
- (2) An "independent mammography supplier" means a facility or entity for the single purpose of performing mammography services. An <u>"independent mammography supplier"</u> is a facility or entity which that is independent of

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the attending or consulting physician's office or group practice, a clinic, an ambulatory surgery center, or a hospital and meets the certification requirements of Section 354 of the Public Health Services Act as implemented by 21 CFRC.F.R.(April 1, 2005) part 900, subpart B and has a valid certificate that has been issued by the U.S. food and drug administration (FDA). Under the Ohio medicaid program all independent mammography suppliers are considered independent diagnostic testing facilities.

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