regulatory requirement. Furthermore, this commenter objected to the preamble reference to violations of other Federal or State law and stated that it is gratuitous to advise the regulated entity or person that compliance with section 1877 of the Act, or regulations promulgated thereunder, does not foreclose citation and adjudication under another Federal or State statutory requirement or regulation.

Response: We disagree. Sections 411.1 and 411.350, as described in the preamble of the proposed rule and as set forth in the proposed regulation, conform to regulation drafting guidelines in explaining the general content of 42 CFR part 411, subpart J. Our intent in including this information, something that is routinely done in any new HCFA regulation, is to provide the public with an outline of the regulation's substantive content.

In this case it is important as well to state what the new regulation does not provide for. Before the proposed rule was published, we received numerous inquiries indicating that the provisions of section 1877 were being confused with the anti-kickback safe harbors specified in the final rule published on July 29, 1991 (56 FR 35952). In fact, the Medicare anti-kickback statute (section 1128B(b) of the Act) and section 1877, while similar in that they address possible abuses of Medicare, are different in scope and application and, therefore, need to be distinguished. The conference report for OBRA '89 includes the following statement:

The conferees wish to clarify that any prohibition, exemption, or exception authorized under this provision in no way alters (or reflects on) the scope and application of the anti-kickback provisions in section 1128B of the Social Security Act. The conferees do not intend that this provision should be construed as affecting, or in any way interfering, [sic] with the efforts of the Inspector General to enforce current law, such as cases described in the recent Fraud Alert issued by the Inspector General. In particular, entities which would be eligible for a specific exemption would be subject to all of the provisions of current law. (H.R. Conf. Rep. No. 386, 101st Cong., 1st session 856 (1989).)

Furthermore, we believe it is our duty to inform the public that lawful conduct under sections 1128B and 1877 of the Act may not be lawful under other Federal statutes or State law or regulations. Conversely, conduct that is lawful under those other authorities may be prohibited under section 1877 and these final regulations.

C. Definitions

1. Clinical Laboratory Services

Under the proposed rule (section 411.353), "laboratory services" are considered to be any services provided by the entities described in section 493.2. The preamble to the proposed rule pointed out at 57 FR 8595 that this would include anatomical laboratory services but would not include noninvasive tests that are not considered clinical laboratory services, such as electroencephalograms or electrocardiograms. Nor would it include x-rays or diagnostic imaging services, such as mammogram and computerized axial tomography scans.

Comment: A few commenters recommended that a definition of "clinical laboratory" be included in the regulations. They suggested that, if the definition used for purposes of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) is to be adopted, that it should be repeated in section 411.351.

One commenter indicated that the definition of clinical laboratory should state the following:

'Clinical laboratory means a facility for the examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings, as described in section 493.2. Such examinations include screening procedures to determine the presence or absence of various substances or organisms in the body. Such examinations do not include noninvasive tests, such as electroencephalograms, electrocardiograms, x-rays or diagnostic imaging services, such as mammogram and computerized axial tomography services.

Response: We agree that this final regulation should contain a definition of clinical laboratory. Thus, based on the definition at section 493.2, which defines a laboratory for CLIA purposes, we are including the following in section 411.351:

Laboratory means an entity furnishing biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Entities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

Comment: One commenter urged that the definition of laboratory services should include a statement that what are considered clinical laboratory services for current procedural terminology (CPT) code purposes are also considered clinical laboratory services for the purpose of these regulations. Thus, in this commenter's opinion, there would be no question about what constitutes clinical laboratory services.

Response: As mentioned in the response to the previous comment, we have defined a clinical laboratory as meaning any laboratory entity that is required to satisfy the CLIA standards in order to perform tests on human beings for "* * * the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings." Therefore, for the purposes of the prohibition on physician self-referral, we are defining "clinical laboratory services" at section 411.351 as follows:

Clinical laboratory services means the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body.

Given this position, the American Medical Association (the organization responsible for CPT) and the CPT publication would not be the references to define the kind of services that are regulated by the physician referral legislation. If individuals want to know what specific tests and test systems are subject to CLIA certification, they may contact the Center for Disease Control and Prevention (CDC), Public Health Service, Attention: CLIA, 1600 Clifton Road, Atlanta, GA 30333. CDC has categorized approximately 12,000 test systems, assays, and examinations for complexity using the criteria at 42 CFR 493.17. CDC publishes notices periodically in the Federal Register to announce additional test systems, assays, or examinations that have been categorized or recategorized since the preceding publication.

For these reasons, we do not support the sole use of CPT codes to identify