

INSURANCE

DEPARTMENT OF BANKING AND INSURANCE

DIVISION OF INSURANCE

**OFFICE FOR THE DEVELOPMENT, IMPLEMENTATION AND DEPLOYMENT OF
ELECTRONIC HEALTH INFORMATION TECHNOLOGY**

Health Benefit Plans

Prompt Payment of Medical Laboratory Claims

Proposed Amendments: N.J.A.C. 11:22-1.1, 1.2, and 1.4

Authorized By: Kenneth E. Kobylowski, Acting Commissioner, Department of Banking and
Insurance.

Authority: N.J.S.A. 17:1-8, 17:1-15(e), 17:1D-3, and 26:1A-132 et seq.

Calendar Reference: See Summary below for explanation of exception to calendar requirements.

Proposal Number: PRN 2012-066.

Submit comments by June 15, 2012 to:

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The agency proposal follows:

Summary

On January 13, 2008, N.J.S.A. 26:1A-132 et seq., the "New Jersey Health Information Technology Act" (the Act), P.L. 2007, c. 330, was enacted. The Act states that it is in the public interest for New Jersey residents to have all appropriate personal health information available to them and to their treating health care professionals in a medical office, hospital emergency room, other health care facility setting, or pharmacy. Further, the Act states that it is the public policy of this State to promote, encourage, facilitate, and support the development, utilization, and improvement of health information technology and electronic health records, including the effectuation of a secure, integrated, and interoperative Statewide health care information infrastructure in accordance with a Statewide health information technology plan that is developed and implemented pursuant to the Act. N.J.S.A. 26:1A-135.

Therefore, as the Act states, it is desirable to implement an electronic health information infrastructure in the context of a Statewide health information technology plan that includes standards and protocols designed to promote patient education, patient privacy, physician best practices, electronic connectivity to health care data, and generally a more efficient and less costly means of delivering quality health care in New Jersey, in order to provide for an interoperative environment among health care providers, health care payers, employers, and patients in New Jersey. N.J.S.A. 26:1A-133.

To further this end, the Act established in the Department of Banking and Insurance the Office for the Development, Implementation and Deployment of Electronic Health Information Technology (Office for e-HIT) and the New Jersey Health Information Technology Commission

(Commission) within the Department of Health and Senior Services. The Commission is required to collaborate with the Office for e-HIT concerning all activities related to the development, implementation, and oversight of the plan and is responsible for approving the Statewide health information technology plan.

A goal of the Office for e-HIT and the Commission is to effectuate health information technology which can eliminate the many different and conflicting standards for collecting and reporting personal health information within the health care community which currently hinder the efficient and appropriate sharing of patient health care information.

This proposal sets forth standards for the collection and reporting of personal health information by medical laboratories. Specifically, the proposal amends N.J.A.C. 11:22-1.1(a) by stating that a purpose of Chapter 22 is the implementation of standards for the collection and reporting of claims relating to medical laboratories.

New definitions are added to N.J.A.C. 11:22-1.2 for Direct Project; Health Level Seven International (HL7); laboratory test; Logical Observation Identifiers, Names and Codes (LOINC); medical laboratory; Office for e-HIT; and Systemized Nomenclature of Pathology Clinical Terms (SNOMED CT).

The definition of “clean claim” is amended to include claims for reimbursements for laboratory tests which have been submitted as required by N.J.A.C. 11:22-1.4(b), which sets forth the minimum requirements for the submission of a claim for laboratory tests.

Proposed new N.J.A.C. 11:22-1.4(b) states that all claims for reimbursements for laboratory tests shall include proof of electronic submission of the results of the tests to the carrier and the medical provider who ordered the tests. If the medical provider does not have the capability to receive the information electronically, test results shall be delivered to that medical provider by

non-electronic means. Once a medical provider has the capacity to receive the information electronically, all test results should be delivered in that manner.

The Direct Project is an initiative of the National Coordinator of Health Information Technology in the United States Department of Health and Human Services which was launched to help expand secure health information exchange efforts by enabling the simple, direct, and secure transport of health information between health care providers at the local level and their patients. The new subsection provides that, unless otherwise specified by the Centers for Medicare and Medicaid Services or the Direct Project at a future date, all laboratory test results shall be reported electronically in HL7 file format and shall include SNOMED CT and LOINC codes where applicable or be reported through electronic submissions that are in compliance with the Direct Project. The proposed amendments further provide that if either the Office of the National Coordinator for Health Information Technology, in the United States Department of Health and Human Services, or the Centers for Medicare and Medicaid Services change the standards for the electronic submission of laboratory tests, the Commissioner, in consultation with the Office for e-HIT, shall issue a notice of administrative changes setting forth the newly revised standards for the submission of electronic laboratory results including acceptable file formats and required codes. The notice of administrative changes shall be published in the New Jersey Register and posted on the Department's website at www.dobi.nj.gov.

A 60-day comment period is provided for in this proposal and, therefore, pursuant to N.J.A.C. 1:30-3.3(a)5, the proposal is not subject to the provisions of N.J.A.C. 1:30-3.1 and 3.2 governing rulemaking calendars.

Social Impact

The proposed amendments will have a positive social impact on all New Jersey residents because, as the Act states, it is in the public interest for New Jersey residents to have all appropriate personal health information available to them and to their treating health care professionals in a medical office, hospital emergency room, other health care facility setting, or pharmacy. In addition, it is the public policy of this State to promote, encourage, facilitate, and support the development, utilization, and improvement of health information technology and electronic health records.

The effectuation of a secure, integrated, and interoperative Statewide health care information infrastructure in accordance with a Statewide health information technology plan will also have a positive social impact on New Jersey physicians and other health care providers, as it will promote electronic connectivity to health care data, physician best practices, patient education, patient privacy and generally a more efficient means of delivering quality health care in New Jersey.

Economic Impact

The electronic transmission of laboratory test results to carriers and providers is an important step in the effectuation of an interoperative Statewide health care information infrastructure will have a positive economic impact on all those who spend monies on health care in this State. The use of health information technology furthers progress toward affordable, safe, and accessible health care by ensuring that health information is available at the point of care for all patients. The use of this technology lessens the expenditure of resources on unnecessarily repeated medical tests while maintaining the highest quality of medical care for New Jersey citizens and, as projected by the Federal Department of Health and Human Services, will reduce the incidence of medical errors. Any such reduction will in turn reduce provider costs, such as high malpractice

premiums resulting from expensive litigation. The Federal Department of Health and Human Services states that such technology could achieve potential savings of almost 10 percent of total health care spending in the United States.

The initial costs for the necessary equipment for sending and/or receiving results of laboratory tests to carriers and medical providers by medical laboratories may have a negative economic impact on the medical provider, the carrier, and the medical laboratory. These costs may be recoverable under the Health Information Technology for Economic and Clinical Health Act (HITECH), which was part of the Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5). Under HITECH, eligible health care professionals and hospitals can qualify for Medicare and Medicaid incentive payments when they adopt certified electronic health record technology and use it to achieve specific objectives. Any costs not recovered are outweighed by the ensuing savings and the increase in efficiency and accuracy that will result from the continued use of such a system.

Federal Standards Analysis

The proposed amendments contain compliance requirements which will require the submission of claims for reimbursements of laboratory tests to include proof of electronic submission of the results of the tests to the carrier providing coverage for the tests. HITECH and the regulations promulgated thereunder, found at 45 CFR Part 170, do not mandate use of electronic reporting of claims, but do require the minimum use of electronic claims submission technology in order to qualify for monetary incentives.

The New Jersey Health Information Technology Act states that it is in the public interest for New Jersey residents to have all appropriate personal health information available to them and to their treating health care professionals in a medical office, hospital emergency room, other health

care facility setting, or pharmacy. Further, the Act states that it is the public policy of this State to promote, encourage, facilitate, and support the development, utilization, and improvement of health information technology and electronic health records, including the effectuation of a secure, integrated, and interoperative Statewide health care information infrastructure in accordance with a Statewide health information technology plan that is developed and implemented pursuant to the Act. It is also desirable to implement an electronic health information infrastructure in the context of a Statewide health information technology plan that includes standards and protocols designed to promote electronic connectivity to health care data, physician best practices, patient education, patient privacy, and generally a more efficient means of delivering quality health care in New Jersey, in order to provide for an interoperative environment among health care providers, health care payers, employers, and patients in New Jersey.

The standards imposed by the proposed amendments are in use throughout the affected industries today and are achievable under currently available technology. Any costs in mandating compliance with these standards are outweighed by the benefits discussed above and in the Social Impact statement.

Jobs Impact

The Department does not anticipate that any jobs will be generated or lost as a result of the proposed amendments. The Department invites commenters to submit any data or studies on the potential job impact of the proposed amendments together with their comments on any other aspects of the proposal.

Agriculture Industry Impact

The proposed amendments will not have any impact on the agriculture industry in New Jersey.

Regulatory Flexibility Analysis

The proposed amendments affect medical providers, insurance carriers, and medical laboratories in this State. Most medical providers and medical laboratories may be considered small businesses under the terms of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16, in that they employ fewer than 100 full-time employees.

The proposed amendments contain compliance requirements which would require the submission of claims for reimbursements of laboratory tests which include proof of electronic submission of the results of the tests to the carrier providing coverage for the tests. All such claims should also include either proof of electronic submission of the test results to the medical provider who ordered the tests if that medical provider has the capability to receive such results electronically, or proof of non-electronic submission of the test results to the medical provider who ordered the tests if that provider is not capable of receiving the data electronically. The intent of the proposed amendments is to establish a component that is necessary to implement an electronic health information infrastructure in the context of a Statewide health information technology plan that includes standards and protocols designed to promote electronic connectivity to health care data, physician best practices, patient education, patient privacy, and generally a more efficient means of delivering quality health care in New Jersey, in order to provide for an interoperative environment among health care providers, health care payers, employers, and patients in New Jersey. Therefore, no differentiation based on business size is appropriate.

The initial costs of compliance for businesses of all sizes are discussed in the Economic Impact above. While professional services may be needed by some businesses to install the systems, the Department does not believe that any professional services will be needed for continuing compliance.

Housing Affordability Impact Analysis

The proposed amendments will not have an impact on housing affordability in this State in that the proposed amendments relate standards for the collection and reporting of personal health information by medical laboratories.

Smart Growth Development Impact Analysis

The proposed amendments will not have an impact on smart growth in this State and it is extremely unlikely that the proposed amendments would evoke a change in housing production in Planning Areas 1 or 2 or within designated centers under the State Development and Redevelopment Plan in New Jersey in that the proposed amendments relate to standards for the electronic reporting of personal health information by medical laboratories.

Full text of the proposal follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

SUBCHAPTER 1. PROMPT PAYMENT OF CLAIMS

11:22-1.1 Purpose and scope

(a) This chapter implements N.J.S.A. 17B:30-26 through 34, which sets standards for the payment of claims relating to health benefit plans and dental plans, **and N.J.S.A. 26:1A-132 et seq., which requires the implementation of standards for the collection and reporting of claims relating to medical laboratories.**

(b) (No change.)

11:22-1.2 Definitions

(a) The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

...

"Clean claim" means:

1. -3. (No change.)
4. The carrier does not reasonably believe that the claim has been submitted fraudulently; [and]
5. The claim does not require special treatment. For the purposes of this subchapter, special treatment means that unusual claim processing is required to determine whether a service or supply is covered, such as claims involving experimental treatments or newly approved medications. The circumstances requiring special treatment should be documented in the claim file[.]; **and**

6. For claims submitted for reimbursement of laboratory tests, that all test results have been submitted as required by N.J.A.C. 11:22-1.4(b).

...

“Direct Project” means an initiative convened by the Office of the National Coordinator of Health Information Technology, within the United States Department of Health and Human Services, to deliver the standards and services required to enable the simple, direct, and secure transport of health information at a more local and less complex level among providers.

“Health Level Seven International (HL7)” means the not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery, and evaluation of health services including the reporting of laboratory test results.

“Laboratory test” means a test performed by a medical laboratory.

“Logical Observation Identifiers, Names and Codes (LOINC)” means universal identifiers for laboratory tests, results, and other clinical observations, incorporated herein by reference, copyrighted by the Regenstreif Institute Inc. and available at loinc.org.

“Medical laboratory” means a clinical laboratory licensed by the State of New Jersey pursuant to N.J.A.C. 8:44.

“Office for e-HIT” means the office established in the Department of Banking and Insurance pursuant to N.J.S.A. 17:1D-1, for the development, implementation, and deployment of electronic health information technology.

“Systemized Nomenclature of Pathology Clinical Terms (SNOMED CT)” means a system of standardized medical terminology developed by the College of American Pathologists, incorporated herein by reference, and owned and maintained by the International Health Terminology Development Organisation at www.ihtsdo.org.

11:22-1.4 Claim submission requirements

(a) A carrier or its agent shall notify its participating health care providers at least annually, and shall make available to covered persons on request, a listing of the type of information and documentation that must be submitted with a claim, including a standard claim form and any other claim submission requirements utilized by the carrier for both manually and electronically submitted claims. Carriers or their agents may change the required information and documentation as long as participating health care providers are given at least 30 days prior notice of the change in the requirements. Carriers or their agents shall also supply participating health care providers with a street address where claim submissions can be delivered by hand or registered/certified mail.

(b) All claims for reimbursements of laboratory tests shall include proof of electronic submission of the results of the tests to the carrier providing coverage for the tests. All such claims should also include either proof of electronic submission of the test results to the medical provider who ordered the tests if that medical provider has the capability to receive such results electronically, or proof of non-electronic submission of the test results to the medical provider who ordered the tests if that provider is not capable of receiving the data electronically.

1. Once a medical provider obtains the capacity to receive laboratory test results electronically, all claims for reimbursement of laboratory tests shall include proof of electronic submission of the test results to that provider.

2. All laboratory test results shall either be reported electronically in accordance with the directives of the Centers for Medicare and Medicaid Services, which as of (effective date of this amendment) require an HL7 file format, version 2.3.1 or higher, incorporated herein by reference (see www.hl7.org), and the inclusion of SNOMED CT and LOINC codes where applicable, or be reported in compliance with the standards propounded by the Direct Project.

3. Upon publication of changes to the standards for electronic submissions made by the Office of the National Coordinator of Health Information Technology or by the Centers for Medicare and Medicaid Services, the Commissioner, in consultation with the Office for e-HIT, shall issue a notice of administrative changes to (b)2 above

setting forth the newly revised standards for the submission of electronic laboratory test results including acceptable file formats and required codes. The notice of administrative changes shall be published in the New Jersey Register and posted on the Department's website at www.dobi.nj.gov.