HEALTH AND SENIOR SERVICES

HEALTH INFRASTRUCTURE PREPAREDNESS AND EMERGENCY RESPONSE

DIVISION OF PUBLIC HEALTH AND ENVIRONMENTAL LABORATORIES

CLINICAL LABORATORY IMPROVEMENT SERVICE

Operation of Clinical Laboratories

Collection stations and patient service centers

Proposed New Rule: N.J.A.C. 8:44-2.14

Authorized By: 

Heather Howard, Commissioner, Department of Health and Senior Services, (in consultation with the Public Health Council, Herbert Yardley, M.A., Chair).

Authority: N.J.S.A. 45:9-42.34 and 26:1A-7

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

Proposal Number: PRN 2009

A public hearing on the proposed new rules will be held between 10 A.M. and 12:00 P.M. on ___ at the following address:

New Jersey Department of Health and Senior Services
First Floor Auditorium
Health and Agriculture Building

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369 South Warren Street (at Market Street)
Trenton, New Jersey 08608

(This address is provided to assist interested persons in obtaining driving
directions by means of computerized mapping programs: Do not mail
comments to this address, as it is undeliverable.)

Persons wishing to comment on the proposal at the public hearing who
wish to be placed on the list of speakers are requested to telephone Ms.
Mary Marks at (609) 984-7923 by ___ and to bring a written copy of their
remarks for submission to the public record.

Submit written comments by ___________ 2009, to:

Ruth Charbonneau, Director
Office of Legal and Regulatory Affairs
NJ Department of Health and Senior Services
PO Box 360
Trenton, NJ 08625-0360

The agency proposal follows:

SUMMARY

The New Jersey Clinical Laboratory Improvement Act, N.J.S.A.
45:9-42.26 et seq., directs the Department of Health and Senior Services,
hereinafter referred to as the Department, to promulgate rules for the
operation of clinical laboratories. See N.J.S.A. 45:9-42.34
Over the past several years, it has been brought to the attention of the Department that the increasing competition for business among clinical laboratories has resulted in some laboratories offering to pay physicians, under the guise of rent, to operate collection stations within the offices used by the physicians for the practice of medicine. In some of these cases, laboratories are approaching physicians who have had laboratory collection stations in their offices for many years operated by competitors who pay no rent because they believe it is a violation of the Federal Stark law (42 U.S.C. §1395nn), the Federal Anti-Kickback statute (42 U.S.C. § 1320a-7b) and guidance issued in the mid 1990’s from the Office of the Inspector General (OIG) of the Federal Department of Health and Human Services (HHS) concerning financial arrangements between laboratories and their customers, including physicians. It should also be noted that in 2008 several physicians in New Jersey were found to have accepted payments for referring patient specimens to an out-of-state laboratory and were heavily fined, forced to disband their medical practice and are subject to further review and action by the State Board of Medical Examiners against their medical licenses. The laboratory owners were sentenced to two years in jail. Court actions have also been taken against physicians in other states for inappropriate financial arrangements with clinical laboratories.
The Department believes that the payment of rent by a laboratory to a physician to operate a collection station in a physician’s office creates a potential conflict of interest between the physician and the laboratory, and constitutes an incentive to the physician to refer specimens to the laboratory in violation of N.J.S.A. 45:9-42.42d, prohibited activities. This statute provides that a clinical laboratory shall not either personally, or through an agent, solicit referral of specimens to his or any other clinical laboratory, or contract to perform clinical laboratory examinations of specimens in a manner which offers or implies an offer of rebates to a person or persons submitting specimens, or fee-splitting inducements, participation in any fee-splitting arrangements or other unearned remuneration. New Jersey Medicaid rules at N.J.A.C. 10:61-2.4 prohibit the payment of rent by clinical laboratories to physicians as a condition of provider enrollment in Medicaid. Some physicians and at least one laboratory have reportedly dropped out as Medicaid providers in order to continue to pay and receive rent for the collection station in the physician's office. In some cases, the rent paid by the clinical laboratory for the small space provided in the physician office is reported to be above fair market value. It is beyond the capacity of the Department to determine what constitutes fair market value. Other states, such as New York, in order to avoid any potential conflict of interest, prohibit a laboratory from operating a collection station in a physician’s office without regard to whether or not
rent is paid. See 10 NYCRR, §34-2.6(c). The Department has considered
prohibiting the operation of collection stations in physician offices
completely. However, these collection stations are of considerable benefit
to the elderly, disabled and other patients who would have to travel to a
patient service center to have blood or other specimens drawn as ordered
by their physician, and the Department does not wish to prohibit this
practice completely at this time provided that the proposed new rules are
successful in stopping and preventing the payment of rent and the
provision of other goods or services by laboratories as an inducement to
physicians to use the laboratory’s services.

Therefore, the Department proposes to prohibit the payment of rent
and other activities such as the sharing of employees between the
laboratories and physicians in order to eliminate the financial incentive to a
physician to refer specimens to a laboratory in violation of N.J.S.A. 45:9-
42.42, and to remove any potential conflict of interest that may be involved
when a laboratory pays rent to operate a collection station in a physician’s
office. A physician’s decision to allow a laboratory to operate a collection
station in his or her office should be based on the benefit to the
physician’s patients, not the payment of rent or the amount of rent a
laboratory is willing to pay or the provision of other goods or services to
the physician. The continued allowance of the payment of rent by clinical
laboratories to operate a collection station in physician offices is contrary
to Medicaid rules, creates a financial interest between the laboratory and
the physician which can result in a conflict of interest, and is considered by
some laboratories to be in violation of the Stark law, the Federal Anti-
Kickback statute and Federal OIG guidance. It is also an unreasonable
burden on the Department to determine in each case if a conflict of
interest exists and whether the rent represents fair market value for the
space or other goods or services provided. This practice may also result
in unnecessary testing and increased costs to the health care system as
patients, whose insurance carriers require they use contracted in-network
laboratories, choose to utilize out-of-network laboratories due to their
convenience.

This proposal continues to permit clinical laboratories to operate
collection stations in physician offices, but prohibits the payment of rent,
sharing of employees or performing or offering other goods or services by
the clinical laboratory.

It should be noted that prior to pursuing this rule proposal, the
Department has twice attempted to address this issue. In May 2001 and
January 2007, the Department advised laboratory directors and owners
that the activities addressed in this rule proposal were considered to be in
violation of N.J.S.A. 45:9-42.42, prohibited activities for clinical
laboratories. These advisories have had no impact and the number of
laboratories engaged in these practices has increased, and the number of

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collection stations in which the laboratories are offering rent and other incentives as an inducement to the physicians to do business with the laboratory have increased substantially. Therefore, the Department has found it necessary to specifically prohibit these activities through the rulemaking process.

Proposed new N.J.A.C. 8:44-2.14(a) would establish criteria for the operation of collection stations in a physician office, which would include: the collection station shall be licensed by the Department; no reimbursement, fees or any other direct or indirect payment shall be made to the physician, including the payment of rent; laboratory staff shall not perform services normally provided by physician office staff; laboratory staff shall not be jointly employed or retained as independent contractors by the physician; except as necessary for the reporting of test results, the laboratory shall not provide office supplies, equipment, waste disposal services, test kits, electronic medical records systems or other goods or services; and, a copy of the signed lease or agreement between the laboratory and the physician shall be made available to the Department upon request.

Proposed N.J.A.C. 8:44-2.14(b) would prohibit the operation of a patient service center/collection station in a physician’s office that is intended to serve the general public, and provides that public patient service centers/collection stations shall be: open to the general public and

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not restricted to serving patients of one or more specific medical practices; located in a free-standing building or occupy space in a public access building; accessed through entrances directly from the exterior or from public hallways or foyers and shall not be accessed through a physician’s office; identified to the public by visible signage on the building exterior and in the building’s directory; and any advertisements or other public notices shall use the address and telephone number of the patient service center. In addition, N.J.A.C. 8:44-2.14(b) would require that the public patient service center/collection station shall be self-contained with regard to all areas of the operation, except that a common waiting area serving all tenants of a building or floor, at least two of which are not referring physicians or health care providers, may be shared. N.J.A.C. 8:44-2.14(c) would also require that a copy of a signed written lease shall be made available to the Department upon request. Proposed new N.J.A.C. 8:44-2.14(c) provides an exception that the patient service center may be located in a professional building which may be owned by a physician or group of physicians, provided that the conditions of this section are met.

As the Department has provided a 60-day comment period for this notice of proposal, this notice is exempt from the calendar requirement pursuant N.J.A.C. 1:30-3.3(a)5.

Social Impact

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The proposed rule affects clinical laboratories that are paying rent to physicians to operate a collection station in physician offices, the physicians who are charging laboratories rent for those collection stations, and the clinical laboratories that operate public collection stations/patient service centers. This proposed rule does not impact the majority of the 700 licensed clinical laboratories in New Jersey that operate approximately 1,600 collection stations, some of which are located in physician offices and which do not pay rent to operate those collection stations in physician offices. Currently, there are 63 independent clinical laboratories, and the Department has received reports that at least 12 of these laboratories are paying rent to physicians to operate collection stations in physician offices. The remaining licensed clinical laboratories consist of hospitals, physician office laboratories, health care facilities and schools. The number of physicians who are collecting rent from the 12 clinical laboratories for collection stations operated in their offices is estimated to be approximately 500, which represents less than ten percent of the estimated 6,500 physician practice sites in New Jersey.

The laboratories that enter into physician office rental arrangements are almost exclusively small to moderate independent laboratories. Historically, over the past twenty years, inspections of smaller independently operated clinical laboratories have found a greater
number and severity of deficiencies than larger independent and other types, such as hospital laboratories. These deficiencies have included failure to perform tests for accuracy; failure to perform or falsification of quality controls to verify test accuracy; unqualified laboratory personnel; referral of proficiency testing specimens; alteration and/or falsification of test results; inadequate supervision by the laboratory director; and improper test performance which adversely affects the accuracy of patient test results and medical treatment decisions. Smaller laboratories have also been found and stopped from offering unproven tests with no known value to patients.

Clinical laboratories will continue to be permitted to operate collection stations in physician offices but they will not be permitted to pay rent or provide other goods or services, such as: laboratory employees performing duties such as answering the phone, making photocopies, filing, or the laboratory paying for supplies, waste disposal, or providing electronic medical record systems for the physician’s practice. The rule proposal would help to ensure that the decision of a physician to allow a clinical laboratory to operate a collection station in his or her office is based on the convenience to the physician’s patients, the reputation of the laboratory for providing prompt, accurate and reliable test results, and the benefit of high quality laboratory findings that assist the physician in making up to seventy percent of medical diagnoses of disease and

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medical conditions in their patients. The decision to allow a clinical laboratory to operate a collection station in a physician’s office should not be based on financial incentives offered by the laboratory. Some small laboratories have advised the Department that they have been forced to pay rent for collection stations in physician offices in order not to lose business to the small number of laboratories that are aggressively pursuing high volume physician practices by offering to pay monthly rent in exchange for the physician’s business.

The Department anticipates that the small number of laboratories paying rent and the relatively small number of physicians who are receiving rent for collection stations in their offices will oppose the rule proposal and state that financial motives are not the basis for selecting a laboratory to operate a collection station in their office. However, it appears the laboratories that do not pay rent because they believe it is in violation of the Federal Stark law and Anti-Kickback statute, OIG guidelines and New Jersey Medicaid rules, have lost business to laboratories offering generous rental payments to operate collection stations in physician offices. It also appears that some laboratories that had never paid rent for collection stations in physician offices have started to pay rent for fear of losing business to the laboratories that are paying rent.
The proposal is intended to ensure that all clinical laboratories in New Jersey operate under the same rules and practices prohibiting the payment of rent or other incentives for physician office collection stations. The great majority of physicians do not have collection stations in their offices and the Department has considered an outright prohibition on physician office collection stations as other states, including New York and Pennsylvania, have adopted. However, the Department recognizes the convenience to both patients and physicians in continuing to allow physician office collection stations. This convenience helps to facilitate patient compliance with laboratory test orders, which may otherwise be delayed or neglected if collection stations are not convenient to the patient.

The proposed rules for the operation of patient service centers are intended to protect the general public and ensure prohibition of the payment of rent for collection stations operated in physician offices which is contained in State Medicaid rules at N.J.A.C. 10:61-2.4. In addition, by prohibiting patient service centers in physician offices that do not truly have the space or intent to serve the general public, the proposal prevents a laboratory from placing its name on the physician door or placing a sign in an office window and claiming that it is serving the general public, thereby allowing the laboratory to pay rent. These efforts by clinical

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laboratories to circumvent existing rules must be prohibited for the above reasons.

For the reasons noted above, and because the proposal should reduce health care costs by limiting referrals to out-of-network laboratories, the proposal would benefit the general public.

Economic Impact

The proposed rules would prohibit a clinical laboratory from paying rent or providing other goods or services to a physician or physician group in exchange for operating a collection station in the physician’s office, and will economically impact a small number of clinical laboratories that engage in this practice. In addition, the physicians who are paid rent by these laboratories will be impacted by no longer being able to collect rent for allowing a clinical laboratory to operate a collection station in their office. The proposed rules for patient service centers/collection stations serving the general public are not expected to have any significant economic impact on the laboratories that are operating patient service centers. There are 700 clinical laboratories that perform testing in New Jersey. These include hospitals, physician office laboratories, health care facilities, schools, independent laboratories and others. The Department has received reports that at least 12 of the 63 independent laboratories are paying rent to physicians to operate collection stations in physician offices. These 12 laboratories operate approximately 500 collection
stations. The Department does not know how many of these collection stations are operated in physician offices, but believes that the majority are in physician offices. The Department does not have any basis by which it can determine the total amount of rent paid to physicians, but some laboratories are known to be paying as much as $3,000 per month for a small office or cubical in the physician’s office. The great majority of the estimated 6,500 physician practices in New Jersey do not have collection stations in their offices as it is not necessary in order to provide laboratory services to their patients. Many patients go to freestanding patient service centers to have their blood drawn for laboratory testing, and many other physician practices have their nurses, medical assistants or phlebotomists draw blood and the specimens are placed in a laboratory provided box in or outside the physician’s office for pick up by laboratory couriers. Although the laboratories that pay, and the physicians who receive rent for collection stations, will object to this rule and claim that the payment of rent has no influence over the selection of a laboratory, a number of laboratories have advised the Department that many physician offices with collection stations operated by laboratories that do not pay rent have terminated longstanding agreements and switched to laboratories that pay rent for the collection station. The laboratories will also claim that the payment of rent helps smaller laboratories compete against larger laboratories. However, there is no escaping the fact that if
the laboratories provide comparable test services, turnaround times, accuracy of test results and customer service, the payment of rent to the physician appears to be the sole basis for the selection of these laboratories and that the payment of rent constitutes an incentive to the physician to refer specimens and conduct business with the laboratory in violation of N.J.S.A. 45:9-42.42. In addition, the appearance of, or the actual conflict of interest that exists when a physician or physician group has a vested financial interest in maintaining the relationship with a laboratory that pays rent for the operation of a collection station in their office cannot be avoided. The proposal seeks to prohibit only the payment of rent or the provision of other goods or services for collection stations located in a physician’s office, which the Department deems inappropriate. The proposed rules do not prohibit a laboratory from paying rent to operate a freestanding, self-contained public patient service center/collection station in a building in which medical practices are located or even in a building that may be owned by physicians, if it chooses to do so and the patient service center is operated in according with this proposal.

Clinical laboratories operating collection stations in physician offices may in some cases cause higher costs to the health care system or to the patient. Many people are restricted by their health insurer to use a particular laboratory. Some laboratories will collect specimens from
patients whose insurer or health plan requires that the patient use a
different laboratory. The unauthorized or out-of-network laboratory
performs the laboratory tests and submits a bill and is reimbursed at an
out-of-network rate. The patient can be responsible for paying a
deductible and the difference between the allowed amount for network
providers and the rate charged by the out-of-network laboratory. The
Department has also been advised that out-of-network laboratories are
frequently reimbursed at a higher rate than network laboratories because
the network of laboratories have agreed to a reduced fee schedule.

As stated in the social impact statement, the Department is
proposing this rule change because it strongly supports the position that
New Jerseyans are best served when the criteria used by a physician or
physician group in determining whether to have a clinical laboratory
operate a collection station in their office are based on benefits to their
patients and not the financial remuneration from the laboratory.

The Department does not anticipate any significant impact from the
proposed rules on its administrative, enforcement or oversight costs.

Federal Standards Statement

The Department is not proposing the new rules prohibiting clinical
laboratories from payment of rent or providing other goods or services to
physicians in order to operate collection stations in physician offices at

N.J.A.C. 8:44-2.14 under the authority of, or in order to implement, comply
with or participate in any program established under Federal law. The Department is proposing the new rules under the authority of N.J.S.A. 45:9-42.26 et seq. and N.J.S.A. 26:1A-7. N.J.S.A. 45:9-42.34 requires that the rules for the operation of clinical laboratories shall equal or exceed minimum standards contained in Federal regulations promulgated pursuant to the “Clinical Laboratory Improvement Act of 1967” (CLIA), 42 USC 263a. As Federal CLIA regulations at 42 CFR Part 493 do not regulate collection stations operated by clinical laboratories, the proposed new rule does not exceed Federal standards and a federal standards analysis is not required.

Jobs Impact
The Department does not anticipate that the proposed rules would result in the generation or loss of jobs in New Jersey.

Agriculture Industry Impact
The proposed rules would not have any impact on the agriculture industry in New Jersey.

Regulatory Flexibility Analysis
Some of the facilities that would be impacted by the proposed new rules and amendments have fewer than 100 full-time employees and, therefore, would be considered small businesses, as the term is defined in the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. The proposed
new rules prohibit clinical laboratories, without regard to size, from paying rent to physicians to operate collection stations in physician offices. As this practice can create a potential or actual conflict of interest that may not be in the best interest of the physician's patients when the selection of a laboratory to operate a collection station is based on a financial interest, no distinction based on the size of the laboratory would be appropriate. The proposed new rules also define the criteria that a public patient service center/collection station shall comply with, including not being operated in a physician office or being restricted to serving patients of one or more specific medical practices.

The proposed new rules would prohibit clinical laboratories with collection stations in physician offices from paying rent or providing other goods or services to the physicians, and would require that patient service centers /collection stations intended to serve the general public shall not be operated in or accessed through a physician office and shall be free-standing and fully self-contained. The Department has determined that it is appropriate for all clinical laboratories to comply with the proposed new rules, regardless of the size of the business.

The proposed new rules do not impose any additional recordkeeping or reporting requirements and the Department does not anticipate that facilities will need to hire any professional services to comply with the new rules because the rules serve only to prevent the
payment of rent or the provision of other goods or services from the laboratory to physicians in exchange for operating a collection station in a physician office, a practice which the Department deems inappropriate and contrary to New Jersey Medicaid rules at N.J.A.C. 10:61-2.4.

Smart Growth Impact

The Department does not anticipate that the proposed new rules would have an impact on the achievement of smart growth or the implementation of the State Development and Redevelopment Plan.

Housing Affordability Impact

The proposed new rules would have an insignificant impact on affordable housing in New Jersey and there is an extreme unlikelihood that the rules would evoke a change in the average costs associated with housing because the proposed new rules concern requirements prohibiting clinical laboratories from paying rent to, or providing other goods or services to physicians in order to operate collection stations in physician offices, and prohibiting the operation of patient service centers/collection stations intended to serve the general public in physician offices.

Smart Growth Development Impact

The proposed new rules would have an insignificant impact on smart growth and there is an extreme unlikelihood that the rules would evoke a change in housing production in Planning Areas 1 or 2 or within Planning Areas 3 or 4.
designated centers under the State Development and Redevelopment Plan in New Jersey because the proposed rules prohibit clinical laboratories from paying rent to, or providing other goods or services to physicians in order to operate collection stations in physician offices, and prohibit the operation of patient service centers/collection stations intended to serve the general public in physician offices.

Full Text of the proposed new rule follows:

8:44-2.14 Collection Stations and patient service centers

(a) A clinical laboratory that operates a collection station in a physician’s office, also known as in-office phlebotomy, shall be limited to collecting specimens from patients of the medical practice in which the collection station is located, and shall comply with the following provisions:

1. The collection station shall be licensed under this chapter and the license shall be prominently displayed in the collection station area;

2. No reimbursement, fees or any other type of direct or indirect payment shall be made to the physician including, but not limited to,
payment of rent or other consideration for the space used for the collection station;

3. Laboratory staff in the collection station shall perform no services for the physician that are normally the responsibility of the physician’s office staff, such as taking patient vital signs or other nursing functions, drawing specimens or performing testing for the physician office laboratory, or performing clerical services;

4. Laboratory staff in the collection station shall not be shared with, jointly employed, or retained as independent contractors by the physician or persons affiliated with the office where the collection station is located;

5. Except as necessary for the reporting of test results, the laboratory shall not provide office supplies, equipment, waste disposal services, test kits for the physician’s own use, electronic medical records systems or other goods or services to the physician; and

6. A copy of the signed lease or agreement shall be made available to the Department upon request.

(b) A patient service center/collection station intended to serve the general public shall not be operated within a physician’s office and shall be:

1. Open to, and serve the general public, and shall not be
restricted to serving the patients of one or more of specific medical practices;

2. Located in a free standing building or occupy a space in a public access building;

3. Accessed directly through an exterior building entrance or from a public access foyer or hallway that clearly identifies the name of the laboratory, and the days and hours of operation;
   i. Access shall not be through a physician’s office.

4. Identified to the public by clearly visible signage on the exterior of the building and listed in the building’s on-site directory;
   i. Advertisements and other public notices by the laboratory shall list the address and telephone number of the patient service center.

5. Self contained with regard to all aspects of the operations including the waiting room, reception area, phlebotomy rooms, restroom facilities and specimen and supply storage areas; except that
   i. The patient service center may share a common waiting area that is used by all the tenants of a building or a floor of the building, provided that two or more tenants renting separate office spaces are not referring physicians or healthcare providers; and

6. A copy of the signed written lease shall be made available to the Department upon request.

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(c) The provisions of this section above shall not be interpreted as prohibiting a laboratory from operating a patient service center in rented space in a professional building which may be owned by a physician or group of physicians provided that the conditions of this section are met.
TO: Public Health Council

FROM: Heather Howard
Commissioner

SUBJECT: Proposed new rules N.J.A.C. 8:44-2.14

Attached for your review and approval is a rule proposal for New Jersey’s 2,300 clinical laboratories. Approximately 700 of these sites are testing laboratories and 1,600 are collection stations.

Currently, clinical laboratories pay an annual fee and proficiency testing (PT) review fees. The proposal would double the current laboratory license fees, which have not been increased since 1998, and eliminate the separate PT review fees. Based on a sample of thirty small, moderate and large laboratories, the net impact on laboratories will be an estimated average increase of 35 percent over the current licensure and PT fees compared to a 34 percent increase in the Consumer Price Index (CPI) from 1998 through January, 2009. Approximately 15 percent of the laboratories will see fee increases greater than 35 percent over and another 15 percent will see increases less than 35 percent. The great majority of laboratories will see a fee increase consistent with the increase in the CPI. The proposed licensure fee increase would be implemented in 2010.

The elimination of proficiency testing fees will result in administrative deficiencies for both the Department and clinical laboratories by significantly reducing the time spent in calculating proficiency testing fees and dealing with the return and re-submission of PT checks and vouchers due to miscalculated fees.

Please let me know if you have any questions.

Attachment