

Extended Mammography Hours for General Hospitals and Hospital Extension Clinics

Effective date: 5/18/16

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Sections 2800 and 2803 of the Public Health Law, Part 405 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon publication in the New York State Register, to read as follows:

A new section 405.33 is added as follows:

405.33 Screening mammography services

(a) *Applicability.* This section shall apply to any general hospital or extension clinic that is certified as a mammography facility pursuant to the Mammography Quality Standards Act (MQSA).

(b) *Extended service hours.*

Any general hospital or extension clinic certified as a mammography facility pursuant to the MQSA shall provide extended hours, i.e. in the early morning, evening, or weekend hours, for screening mammography services. Extended hours for screening mammography services shall be provided on at least two days each week, for at least two hours each day offered, for a total of at least four hours each week, including but not limited to the following times:

- (1) Monday through Friday, between the hours of 7:00 a.m. and 9:00 a.m.;

- (2) Monday through Friday, between the hours of 5:00 p.m. and 7:00 p.m.; or
- (3) Saturday or Sunday, between the hours of 9:00 a.m. and 5:00 p.m.

(c) *Waiver.*

- (1) A facility may submit an application for a waiver from the requirements of this section, in whole or in part, if it can demonstrate, to the Department's satisfaction, that the facility:
 - (i) does not have sufficient staff to provide extended hours for screening mammography services in accordance with this section, and that it is making diligent efforts to obtain staffing such that it can provide extended hours;
 - (ii) is in the process of discontinuing screening mammography services, as part of a consolidation or similar change; or
 - (iii) is subject to such other hardships as the Department deems appropriate.
- (2) The Department may deny, grant or extend a waiver for 90 days, or more if the Department determines appropriate, in its sole discretion.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (“PHL”) Section 2800 provides that “hospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state . . ., the department of health shall have the central, comprehensive responsibility for the development and administration of the state’s policy with respect to hospital related services . . .”

PHL Section 2803 authorizes the Public Health and Health Planning Council (“PHHPC”) to adopt rules and regulations to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities.

Legislative Objectives:

The legislative objectives of PHL Article 28 include the protection of the health of the residents of the State, by promoting the availability of high quality health services at a reasonable cost.

Needs and Benefits:

In 2014, nearly 22% of women in New York State (NYS) aged 50-74 reported not receiving mammograms at least every other year. Breast cancer is the most commonly diagnosed cancer and the second leading cause of cancer death among women in New York State. Each year, approximately 15,000 women in New York State are newly diagnosed with

breast cancer, and approximately 2,640 die from the disease. Some subpopulations who are less likely to have been screened include women without health insurance (61.7% screened) and women without a regular health care provider (63.0% screened). Screening for breast cancer can increase the likelihood of identifying cancer at an early stage, when treatment is most successful. Once screened, follow-up diagnostic testing is critical to ensuring women receive necessary, potentially life-saving treatment.

Women may not get screened because they are afraid that mammography may be painful, they do not know what screening guidelines are, they do not know where to go for screening, they may have transportation barriers, or they may think screening is unaffordable. When women need follow-up testing and treatment, they can be overwhelmed. They may need help with accessing services, navigating complex health systems, and managing treatment decisions. The Community Preventive Services Task Force, an independent panel of experts appointed by the Centers for Disease Control and Prevention (CDC), has recommended reducing structural barriers as an intervention to improve breast cancer screening. Reducing structural barriers includes modifying hours of service to meet client needs.

There are approximately 600 certified mammography facilities in New York State: 210 are hospital-based (152 hospital locations, plus 58 hospital extension clinic sites); 18 free-standing diagnostic and treatment center; and 372 other non-hospital based mammography facilities. A survey of 36 contractors in the Cancer Services Program, which provides cancer screening for the uninsured, found that the majority (95%) had at least one mammography provider (either hospital or nonhospital based) that offered extended hours. A recent review of

160 of 210 hospital-based mammography facilities in NYS found that 70% offer one or a combination of alternative hours of services (early morning, evening, or weekend), and 30% do not.

Costs:

Costs to the State Government:

The proposed rule does not impose any new costs on state government.

Costs to Local Government:

The proposed rule does not impose any new costs on local governments, with the exception of four general hospitals that are operated by local governments. The cost to local governments that operate general hospitals are the same as the costs to private regulated parties, as described below.

Costs to Private Regulated Parties:

Both the Affordable Care Act and the NYS Insurance Law require insurers to cover mammography. Facilities already obtain third-party payment for mammograms through Medicaid and other insurers, thereby reducing the cost to regulated parties. Further, these proposed rules are not expected to impose any additional costs on those hospitals that are already in compliance, and the 70% of hospital-based facilities that already offer some form of extended hours.

The primary cost for those facilities that will be required to extend or change their hours for screening mammography services, assuming they are not already offering such hours, is the cost of ensuring staff, such as technicians, radiologists, and intake and support staff, are available

to satisfy the extended hour requirement. The Department expects that most hospitals and hospital extension clinics that currently offer extended hours can modify the work hours of existing staff or use flex time to avoid incurring additional staff costs. Those facilities that need to modify their appointment hours to comply with these regulations may be able to use similar scheduling strategies to avoid incurring any new costs.

Costs to the Regulatory Agency:

The proposed rule does not impose any new costs on any regulatory agency.

Local Government Mandates:

The four general hospitals that are operated by local governments will be required to comply with this regulations, as discussed above.

Paperwork:

The proposed rule imposes no new reporting requirements, forms, or other paperwork upon regulated parties.

Duplication:

There are no relevant rules or other legal requirements of the Federal or State governments that duplicate, overlap, or conflict with this rule.

Alternatives:

There were no significant alternatives to be considered during the regulatory process. The serious risk that breast cancer presents justifies requiring extended hours for screening mammography services.

Federal Standards

The proposed rule does not exceed any minimum standards of the federal government for the same or similar subject area. Although the Mammography Quality Standards Act (MQSA) governs certain aspects of mammography services, it does not govern the hours at which such services must be available.

Compliance Schedule:

The proposal will go into effect upon publication of the Notice of Adoption in the *New York State Register*.

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REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect of Rule:

The proposed rule will apply to the 152 hospitals and 58 hospital extension clinics providing screening mammography services in New York State. Of these, there are four hospitals run by a local government (county) and one hospital that qualifies as a small business. Facilities that are small businesses or operated by local governments will not be affected differently from other facilities.

Compliance Requirements:

Compliance requirements are applicable to the one hospital considered a small business as well as the four hospitals operated by local governments. Compliance requires providing extended hours for screening mammography services.

Professional Services:

As noted in the Regulatory Impact Statement, this regulation will require additional staffing or staffing adjustment to ensure that screening mammography services are available at the required hours.

Compliance Costs:

Compliance costs for small businesses and local governments would be the same as those described in the Regulatory Impact Statement.

Economic and Technological Feasibility:

It is economically and technologically feasible for facilities that are small businesses or operated by local governments to comply with this amended rule.

Minimizing Adverse Impact:

Approximately 70% of hospital-based mammography facilities already offer some form of extended hours. By adopting a regulatory standard for which this is already a significant level of compliance, the Department has minimized the impact on regulated facilities. Additionally, the regulation includes a waiver provision for those facilities that can demonstrate hardship.

Small Business and Local Government Participation:

A copy of this notice of proposed rulemaking will be posted on the Department's website. The notice will invite public comments on the proposal and include instructions for anyone interested in submitting comments, including small businesses and local governments.

Cure Period:

Chapter 524 of the Laws of 2011 requires agencies to include a "cure period" or other opportunity for ameliorative action to prevent the imposition of penalties on the party or parties subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one was not included. This regulation creates no new penalty or sanction. Hence, a cure period is not required.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

The proposed rule will apply to the 152 hospitals and 58 hospital extension clinics providing screening mammography services in New York State. The Department identified 57 hospitals and 13 hospital extension clinics providing mammography facilities located in rural areas of the State, defined as counties with less than a population of 200,000. A review of the hospital screening mammography services determined that 67% already offer some form of extended hours. Since this percentage is similar to the statewide percentage of approximately 70% of facilities already offering some form extended hours, this proposed rule is not expected to have a disproportionate impact on rural areas.

Reporting, Recordkeeping, Other Compliance Requirements and Professional Services:

This regulation will require additional staffing or staffing adjustment to ensure that extended screening mammography services are available.

Costs:

Compliance costs for entities in rural areas would be the same as those described in the Regulatory Impact Statement.

Minimizing Adverse Impact:

Approximately 67% of facilities in rural areas are already offering some form of extended hours. By adopting a regulatory standard for which this is already a significant level of

compliance, the Department has minimized the impact on facilities. Additionally, the regulation includes a waiver provision for those facilities that can demonstrate hardship.

Rural Area Participation:

A copy of this notice of proposed rulemaking will be posted on the Department's website. The notice will invite public comments on the proposal and include instructions for anyone interested in submitting comments, including those from rural areas.

JOB IMPACT STATEMENT

No Job Impact Statement is included because the Department has concluded that the proposed regulatory amendments will not have a substantial adverse effect on jobs and employment opportunities. The basis for this conclusion is that requiring extended hours for screening mammography services does not reduce employment opportunities, and may create employment opportunities.

ASSESSMENT OF PUBLIC COMMENT

Public comments were submitted to the NYS Department of Health (Department) in response to the proposed regulation. The public comment period for this regulation ended on March 28, 2016. The Department received comments from the New York State Radiological Society, the Healthcare Association of New York State, the New York City Health and Hospitals Corporation, the Greater New York Hospital Association, and Memorial Sloan Kettering Cancer Center. The Healthcare Association of New York State and other commenters appreciate the existence of an exemption process. Supportive comments were also submitted by numerous American Cancer Society-Cancer Action Network volunteers and the American Cancer Society-Cancer Action Network. These comments and the Department's responses are summarized below:

COMMENT: The New York State Radiological Society (NYSRS) and Memorial Sloan Kettering Cancer Center (MSK) requested the replacement of the term “mammography services” with “screening mammography services,” expressing concern over staffing challenges presented by offering more complex procedures during extended hours.

RESPONSE: The intent of the proposed regulation is to increase screening rates by removing structural barriers to screening, and the term “mammography services” in the proposed rule was intended to refer only to screening mammography services. The Department agrees with the comment and has changed the term to “screening mammography services” in the final rule adoption.

COMMENT: NYSRS, MSK, the Healthcare Association of New York State (HANYs), the Greater New York Hospital Association (GNYHA), and the American Cancer Society-Cancer

Action Network (ACSCAN) and other commenters requested flexibility in the hours and days appointments must be offered by eliminating the consecutive hours mandate.

RESPONSE: The intent of the proposed regulation is to increase screening rates by increasing the availability of convenient appointment times for screening mammography services. The regulation achieves this by ensuring that at least four hours of extended hours are provided, on two separate days. For example, an 8:00 a.m. to 6:00 p.m. offering would meet the requirement of the regulation, for one of the required days. In addition, the extended hours do not need to be in addition to a full 9:00 a.m. to 5:00 p.m. offering; facilities can adjust staffing and appointment schedules to allow for early or late hour appointments, to avoid incurring additional staff costs. For example, a 10:00 a.m. to 7:00 p.m. offering would meet the requirements of the regulation, for one of the required days. Additionally, facilities that are not able to meet this requirement may submit an application for a waiver for the Department's consideration. The Department believes that, in this way, the regulation provides the appropriate degree of flexibility.

COMMENT: NYSRS requested that the regulations be changed to instead require 10 additional hours per month that are outside of the standard work week.

RESPONSE: The proposed rule sets the expectation of at least four hours a week outside the standard work day with the option of offering at least two of those hours on the weekend.

Limiting extended hours to only 10 hours per month does not address the intent of the proposed rule.

COMMENT: GNYHA proposes that the rule reflect that the four-hour requirement can fully be met by offering weekend hours.

RESPONSE: The regulation requires that extended hours be provided on at least two days each week. Hence, a facility could meet this requirement by offering extended hours on both Saturday

and Sunday. However, if extended hours are offered on only one weekend day, then extended hours must be offered on at least one weekday as well.

COMMENT: HANYS proposed that the regulation allow each facility to evaluate the outcomes and benefits of the extended service hours provision after a specific time period to validate the extent of the need in all areas.

RESPONSE: The proposed rule does not limit a facility from conducting a utilization assessment to evaluate the outcomes and benefits of the extended hours being offered. If a facility determines that extended hours are not being utilized in a particular community and the provision of extended hours is causing an undue hardship to continue, a facility may submit an application for a waiver for the Department's consideration.

COMMENT: GNYHA notes that the 90 day waiver may not allow enough time for an issue to be resolved. Further, GNYHA proposes an additional waiver criteria be added if a provider can demonstrate a lack of demand for alternate hours services.

RESPONSE: The proposed rule does not limit a facility from conducting a utilization assessment to evaluate the outcomes and benefits of the extended hours being offered. If a facility determines that extended hours are not being utilized in a particular community and the provision of extended hours is causing an undue hardship to continue, a facility may submit an application for a waiver for the Department's consideration. The Department also has discretion to issue waivers for more than 90 days, where appropriate.

COMMENT: MSK and NYSRS recommended that the proposed rule be applicable across an entire health care system or multi-site institution rather than each individual location within these types of systems.

RESPONSE: This proposed rule addresses an important structural barrier to the receipt of screening mammography services – the availability of convenient appointment times. The proposed rule applies to any general hospital or extension clinic certified as a mammography facility in accordance with the Mammography Quality Standards Act. Health systems with multiple mammography facilities may have such facilities located in various regions. To limit the rule to only an individual location within a health system would limit the geographical reach of the extended hours in some areas. Because transportation is an additional barrier to the receipt of screening mammography services, it is important that all relevant mammography facilities offer extended hours. If a facility determines that extended hours are not being utilized in a particular community and is causing an undue hardship to continue, or determines that it is unable to offer extended hours at a particular location due to a specific reason, a facility may submit an application for a waiver for the Department’s consideration.

COMMENT: A commenter noted that evening and weekend hours offered at that facility were not well utilized by patients and are thus not necessary. Early morning and late afternoon hours were more successful.

RESPONSE: The proposed rule allows facilities to consider their extended hour offerings as early morning, evening, or on the weekends. If a facility determines that extended hours are not being utilized in a particular community and the requirement is causing an undue hardship, a facility may submit an application for a waiver for the Department’s consideration.

COMMENT: A commenter noted that the rule may place an undue staffing burden on a small, rural hospital.

RESPONSE: The proposed rule includes a waiver process in the instance that a facility either does not have sufficient staff to provide the extended hours or does not have the resources to hire additional staff.

COMMENT: NYSRS and other commenters requested clarification that the proposed rule does not require a facility to expand their hours of operation beyond a 40 hour work week.

RESPONSE: The proposed rule does not require a facility to expand the work week for its employees. A facility may adjust its current hours for screening mammography services to ensure that it is satisfying this new requirement; facilities may be able to meet this requirement by providing different hours of service availability than they are currently providing, rather than increasing the total hours of service availability. The Department expects that most hospitals and hospital extension clinics that currently offer extended hours can modify the work hours of existing staff or use flex time to avoid incurring additional staff costs. The proposed rule includes a waiver process in the instance that a facility either does not have sufficient staff to provide the extended hours or does not have the resources to hire additional staff.

COMMENT: NYSRS recommended amending Insurance Law to require all insurance companies cover annual mammography for women 40 years of age and over without cost sharing.

RESPONSE: The Department does not have the authority to amend the Insurance Law. Accordingly, no change is made to the regulation.

COMMENT: ACSCAN suggests that additional interventions such as education, patient reminders and mobile mammography could further improve New York's breast cancer screening rates.

RESPONSE: The Department takes this comment under advisement. Because the suggestion is outside the scope of the proposed regulation, the Department has not made changes to the final regulation.