within Schenectady, changes to certain rules are necessary. Additionally, an unnecessary subdivision in the Division of Lottery rules is also proposed to be eliminated. Because this rulemaking simply updates the Commission's address in various rules, the Commission does not anticipate public comment and no person is likely to object to the proposed revisions.

Job Impact Statement

A job impact statement is not required for this consensus rulemaking proposal because the proposed amendments will not adversely affect jobs or employment opportunities.

This proposed rulemaking will update the New York State Gaming Commission's address in various rules. Additionally, an unnecessary subdivision in the Division of Lottery rules is also proposed to be eliminated.

The proposed amendments will not have an impact on jobs or employment opportunities.

Department of Health

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Ionizing Radiation

I.D. No. HLT-15-24-00003-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed Action: Repeal of Part 16; addition of new Part 16 to Title 10 NYCRR.

Statutory authority: Public Health Law, section 225

Subject: Ionizing Radiation.

Purpose: Compatibility with federal standards and modernization to reflect current technology.

Substance of proposed rule (Full text is posted at the following State website: https://regs.health.ny.gov/regulations/proposed-rule-making): The regulatory proposal would repeal and replace all sections within Part 16 of Title 10 of the New York Codes, Rules and Regulations (NYCRR), as described in more detail below:

Section 16.1 is updated to correct references to other agencies and persons exempted under Title 10 of the Code of Federal Regulations (CFR) Part 30.

Section 16.2 is updated to include numerous new definitions used in 10 CFR Part 30, as well as other definitions related to new technologies, updated units and clarification of terms.

Section 16.4 updates appendix references, including changing the reference from 10 NYCRR Part 16 to application sections within 10 CFR Part 30.

Section 16.5 updates responsibilities for radiation safety to include acceptance testing and annual program review requirements.

Section 16.6 makes updates to the requirements for evaluating prior occupational doses and removes provisions on planned special exposures. The term "eye dose" is replaced by "lens dose."

Section 16.7 updates dose limits for members of the public to reflect current Title 10 CFR references and outdated language is removed or updated.

Section 16.10 is amended to update inspection schedules, add Certified Radiation Equipment Safety Officer (CRESO) program requirements, and update requirements for surveys and testing of sealed sources.

Section 16.11 is updated to reflect changes in terminology for personnel monitoring and to clarify dose limits.

Sections 16.12, 16.13 and 16.15 are all updated to reflect 10 CFR Part 30 references instead of references to 10 NYCRR Part 16, as well as to clarify the actual language and phrasing used within these sections.

Section 16.14 is updated to require recording of high patient doses from fluoroscopy and notification of referring physician and instructions to patient.

Sections 16.16 and 16.17 are updated for compatibility with 10 CFR Part 30 requirements.

Section 16.19, concerning limitations on application of radiation to humans, is updated to reflect changes in the use of radioactive materials especially therapeutic sources.

Section 16.22 is updated to remove the requirement for mammography screening programs to teach breast self-examination.

Section 16.23 is updated to require quality assurance (QA) programs for advanced modality dental and podiatry, to require radiation safety policies regarding patient fluoroscopy doses and neonatal imaging, to update specifications for modern imaging modalities, and to update breast imaging QA requirements.

Section 16.24 is updated to reflect updates to QA requirements and verification of radiation therapy treatments.

Section 16.26 is updated to incorporate by reference the current federal regulation from the U.S. Nuclear Regulatory Commission (NRC).

Sections 16.40 and16.41 are updated to reflect new fee schedules and to incorporate NYS Department of Labor (DOL) fee categories.

Section 16.50 is updated to correctly reference the New York City Department of Health and Mental Hygiene (NYC DOHMH), change registration periods to allow more flexibility, and include commercial requirements previously listed within DOL regulations.

Section 16.51 is updated to include several items in the prohibited uses of radiation equipment, and half-value layer tables were updated to be current with federal manufacturing requirements (21 CFR Part 1020) for equipment listed in sections 16.52 through 16.70 of Title 10 of the NYCRR.

Sections 16.52, 16.54 and 16.55 are updated to include specifications for hand-held units and Cone Beam Computed Tomography (CBCT) as well as updates to filtration requirements. Requirements for gonadal shielding have also been removed.

Section 16.53 is updated to include changes for handheld intra-oral radiographic equipment.

Section 16.58 is updated to include new specifications for display of air kerma and minimum source to skin distance, to be consistent with federal manufacturing requirements (21 CFR Part 1020).

Sections 16.60 and 16.61 are updated to reflect current technologies and therapy equipment operated at potentials over and below 60 kV.

Section 16.65 is a new section regarding CBCT quality assurance, physicist testing, and accreditation requirements.

Section 16.101, concerning licensure, is updated to incorporate references to the CFR. Although no additional requirements are being added, elements of 10 CFR Part 31 and the Appendices to Part 16 are now included herein.

Section 16.102 is updated to add a paragraph on authorizing the Department to inspect a facility prior to the issuance of a license and adds a paragraph requiring an emergency plan for licensees that possess large amounts of dispersible radioactive material. This was previously codified in DOL regulations under 12 NYCRR Part 38. This section also adds conditions for consortiums to share accelerator produced isotopes.

Section 16.103, concerning licensing requirements for radioactive materials, incorporates by reference various provisions within 10 CFR Parts 30, 40, and 70 for licensing requirements. Currently these requirements are only incorporated into license conditions but not NYS regulations.

Section 16.104 adds requirements on portable gauge security, consortiums, and breakthrough limits for generators.

Section 16.109 adds reciprocity agreement provisions with other Agreement States, which were previously codified in DOL regulations within 12 NYCRR Part 38. This new section will also allow a licensee to pay a fee to work in New York for up to 180 days each year, instead of only allowing licensees to work 30 days each year but at no charge.

Section 16.112 is updated to add requirements for increased security for certain amounts of radioactive material, as required by 10 CFR Part 37.

Sections 16.113 and 16.114 add requirements for decommissioning and financial assurance.

Section 16.123 updates medical use requirements for specific licenses for certain medical uses of byproduct materials, to be compatible with Federal regulations.

Section 16.124 is a new section that adds manufacturing requirements for licenses to manufacture or transfer certain items containing radioactive material.

Section 16.125 is a new section that adds additional requirements for the manufacture, preparation or transfer for commercial distribution of medical drugs containing radioactive material.

Section 16.126 adds a new requirement for sealed source and device registration.

Section 16.127 adds a new section governing licenses for industrial radiography as well as radiation safety requirements for industrial radiographic operations.

Section 16.128 adds a new section for well logging.

Section 16.129 adds a new section for panoramic irradiators.

Text of proposed rule and any required statements and analyses may be obtained from: Katherine Ceroalo, DOH, Bureau of Program Counsel, Reg. Affairs Unit, Room 2438, ESP Tower Building, Albany, NY 12237, (518) 473-7488, email: regsqna@health.ny.gov

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 60 days after publication of this notice.

Regulatory Impact Statement

Statutory Authority:

Section 7 of Part B of Chapter 58 of the Laws of 2006 sets forth the authority for the Commissioner of Health to modify or abrogate the regulations found in Part 38 of Title 12 (Labor) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) pertaining to the radiation control program.

The Public Health and Health Planning Council is authorized by § 225(4) of the Public Health Law (PHL) to establish, amend, and repeal provisions of the State Sanitary Code (SSC), subject to the approval of the Commissioner of Health. PHL §§ 225(5)(p), (q) and 201(1)(r) authorize SSC regulations to protect the public from the adverse effects of ionizing radiation. Pursuant to such statutory authority and as set forth in 10 NYCRR Part 16, the Department of Health (Department), licenses or registers health care providers to use radioactive materials or ionizing radiation emitting equipment on patients.

The federal Atomic Energy Act of 1954 (the Act), codified at 42 USC §§ 2021, et. seq., authorizes the United States Nuclear Regulatory Commission (NRC) to regulate the use of radioactive materials. The Act also authorizes ''Agreement States,'' to regulate the use of radioactive materials in lieu of the NRC, provided that the ''Agreement State'' promulgates regulations that are comparable to or exceed NRC's regulatory standards. New York State is an ''Agreement State'' within the meaning of the Act. New York's regulatory standards for the use of radioactive materials in 10 NYCRR Part 16 must therefore meet or exceed comparable NRC regulatory standards. The Act governs only the use of radioactive materials: it does not apply to x-rays or radiation therapy equipment that emit only x-rays.

Legislative Objectives:

Chapter 58 of the Laws of 2006 transferred the radiation control program from the Department of Labor (DOL) to the Department of Health, effective July 1, 2006. The law specifically sets forth that the regulations (12 NYCRR Part 38) would remain in effect until "duly modified or abrogated by the Commissioner of Health." The amendments being made by this regulation to 10 NYCRR Part 16 will incorporate and update the regulatory provisions currently found in 12 NYCRR Part 38. It is therefore appropriate to repeal 12 NYCRR Part 38 in its entirety.

The legislative intent of PHL §§ 225(5), 201(1)(p) and (q) are to protect the public from the adverse effects of ionizing radiation. Promulgating regulations to ensure safe and effective uses of radioactive material and radiation producing equipment is consistent with this legislative objective. Section 225(5)(q) of the Public Health law also authorized the Department to recover the cost of the programs by charging adequate and reasonable fees for its regulatory activities. Such fees enable the program to maintain the staffing level required to meet the legislative mandate. By establishing the Special Revenue Operating fund in 1999 the Legislature intended the program to be funded through fees.

Needs and Benefits:

The US Nuclear Regulatory Commission (NRC) has relinquished its authority to regulate the use of radioactive materials in New York State to the State. The Atomic Energy Act of 1954 (the Act) (codified at 42 USC § 2021 et. seq.) requires New York to adopt and enforce regulatory standards for the use of radioactive materials that are comparable to or exceed federal regulatory standards that apply to the use of radioactive materials. The Department regulates approximately 1,100 facilities that use radioactive material and approximately 10,000 facilities that use x-ray equipment. The proposed regulations incorporate by reference many of the NRC regulatory standards that govern the use of radioactive materials in medical and commercial settings. In recent years the technology and equipment used to deliver radiation therapy to cancer patients, including systems used to plan and execute radiation therapy treatment, have become significantly more complex. Recently developed radiation therapy systems more effectively deliver high-dose rate treatments to precisely defined three-dimensional tumor volumes while sparing doses to healthy tissue. Patients benefit significantly when, as is the case in most of such radiation treatments, the dose is delivered as intended.

Schedules for licensing and registration fees currently being assessed by the Bureau of Environmental Radiation Protection (BERP) are published under two separate Titles of the NYCRR. Title 12 NYCRR section 82.8 contains the fee schedule for radioactive materials licenses and radiation equipment registrations issued to industrial and commercial facilities formerly regulated by DOL under Industrial Code Rule number 38 (12 NYCRR 38). Title 10 NYCRR section 16.41 contains the corresponding schedule for radioactive sources regulated by the Department under 10 NYCRR Part 16. The current proposal combines these into one fee schedule to be published in 10 NYCRR § 16.41. Regulated parties would benefit from having a single fee schedule in one location for all radiation sources regulated by the Department.

The current fee schedules were established in 2001 (for the Department) and 2005 (for DOL). The costs of the Department's program have increased due to increased salary, equipment, and travel costs. In addition to these cost increases, increased security measures have been adopted requiring closer tracking and more frequent inspection by the Department of certain radiation sources that are of concern for national security reasons. The increased costs from these additional measures must be recovered through fees.

Finally, the proposed rule establishes an annual fee for reciprocity. Reciprocity is required under federal rules as it allows an entity licensed in another state to operate temporarily in New York based on their radioactive materials license in their home state. New York is currently one of only two states that does not charge a reciprocity fee (the other is Alabama). Other states' fees (including 48 other state programs) range from $100 to $1,400 with an average fee of about $900 per year.

The NRC audited New York State in August 2022 to review the overall status of the agreement state program. A significant finding of the last two such audits was that the New York State program is failing to meet compatibility standards. Since this is the third audit where NYS was deemed not compatible with NRC regulations, NRC placed NYS on heightened oversight. This status will be maintained until these regulations are updated and NRC completes another audit.

Costs:

Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity:

This regulation updates the fees charged to facilities that use radioactive materials or x-ray equipment. On average the fee increases are 68% over existing fees. These fees are still significantly less than the corresponding fees charges by the NRC which, depending on facility type range from $12,300 to over $53,800, or two to six times higher than the proposed fees. Geographically adjacent states (PA, NJ, and MA) have different fee structures that are more variable, but in general their fees are slightly higher than what the Department is proposing in this rule.

Fee Category	Current fee	Proposed fee	Count
Radiation Equipment Category I (i.e., Hospital)	$1,420	$2,600	75
Radiation Equipment Category II (i.e., Clinic)	$1,080	$1,800	200
Radiation Equipment Category III (i.e., Large Private practice)	$740	$1,250	200
Radiation Equipment Category IV (i.e., Small Practice)	$325	$550	600
Radiation Equipment Category V (i.e., Small Practice Low Volume)	$190	$325	1,400
Radiation Equipment Category VI (i.e., Dental/Vet/Podiatry)	$65	$100	7,400
Radioactive Materials Category I (i.e., Medical Broadscope)	$5,265	$9,600	6
Radioactive Materials Category II (i.e., Academic Broadscope)	$3,510	$6,200	9
Radioactive Materials Category III (i.e., Nuc Pharm, Brachytherapy)	$1,400	$2,400	37
Radioactive Materials Category IV (i.e., Nuclear Medicine, LINAC)	$880	$1,500	502
Radioactive Materials Category V (i.e., Clinical Labs, XRF)	$350	$600	78
Radioactive Materials Category VI (i.e., Gas Chromatograph)	$50	$120	2
Radioactive Materials Commercial 1 (i.e., Industrial Radiography)	$2,500	$3,600	52
Radioactive Materials Commercial 2 (i.e., Manufacturing)	$1,833	$3,000	23
Radioactive Materials Commercial 3 (i.e., R&D, Irradiators)	$1,333	$2,400	148
Radioactive Materials Commercial 4 (i.e., Gauges)	$1,000	$1,800	182
Radioactive Materials Commercial 5 (i.e., GC, analytic Equipment)	$500	$600	5

Fee Category	Current fee	Proposed fee	Count
Radioactive Materials General (i.e., General License)	$33	$120	146
Totals (count x fee)	$2,555,458	$4,291,760	11,065

Additionally, these regulations will impose new costs on Cone-Beam CT units (CBCTs). These units, like all other CT units, will have to be accredited within 18 months of the adoption of this rule. They will also be subject to annual quality assurance testing. Accreditation costs are approximately $3,000 every three years, and the annual Quality Assurance (QA) testing will be $800 to $1,200 per year.

Costs to State and Local Governments:

Government agencies are exempt from the fees in these regulations, except for government operated hospitals and higher education institutions. This will include about 30 hospitals (including Nassau County Medical Center, Westchester County Medical Center, and Erie County Medical Center) and State University of New York (SUNY) colleges who will have an approximately 60% to 75% increase in fees.

The cost increase to the three county run health care facilities are listed below:

County	Current Fees	Proposed Fees	Net increase
Nassau	2300	4100	+1800
Westchester	3635	5875	+2240
Erie	1960	3300	+1340

There are approximately 25 SUNY facilities that have X-ray equipment or a radioactive materials license. The sum of all SUNY fees will increase from approximately $36,000 currently to a total of $63,000 spread over the 25 regulated facilities. These fee increases are incidental costs for programs of this size.

Costs to the Department of Health:

These regulations make numerous technical changes and updates to the radiation safety rules. These changes will require the Department to update guidance, forms, and Standard Operating Procedures. These activities are done periodically and will not incur significant extra costs for the Department.

Local Government Mandates:

These proposed regulations apply to hospitals operated by public benefit corporations including Nassau, Erie and Westchester Medical centers. The increased annual fees will apply to these facilities. Registrants and licensees, including the hospitals operated by state and local governments, are currently required to retain all quality assurance documents for review by the Department. As such, no other additional costs or mandates are associated with implementation of these regulations.

Paperwork:

Department regulations (10 NYCRR Part 16) require registrants and licensees to maintain a variety of records relating to the use of ionizing radiation for review by the Department. The Department estimates that licensees and registrants may have a small amount of additional documentation to create, maintain, or file these records. These regulations change the content of those records (ex. different quality assurance requirements) but do not significantly increase any required documentation over the current standards.

Duplication:

There is no duplication of the proposed regulatory requirements by any federal, state, or local agency for licensees, registrants, or authorized users subject to 10 NYCRR Part 16. New York State entered into an agreement with the federal government on October 15, 1962, by which the federal government discontinued its regulatory authority over the use of radioactive materials and New York assumed such authority.

Alternatives:

Many of the regulatory changes are required to meet federal standards. The alternative to the present fee proposal is to leave the current fees unchanged. This would require a proportional reduction in the scope of the Department's regulatory program to offset the effects of inflation and increased security measures. Failure to implement these changes would jeopardize the agreement state status and could also jeopardize public health.

Federal Standards:

New York State's agreement with the NRC requires it to promulgate regulations consistent with the NRC's rules, either by incorporation by reference or by developing state rules that are nearly identical. These regulations incorporate by reference many federal standards developed by the U.S. NRC.

Compliance Schedule:

Except for the Cone-Beam CT accreditation requirements, there is no compliance schedule imposed by these regulations, which shall be effective upon publication of the Notice of Adoption in the State Register. The Cone-Beam accreditation rule requires that facilities apply to an accrediting body within 90 days of the regulations going into effect and that they complete the process with 18 months.

Regulatory Flexibility Analysis

Effect of Rule:

These regulations will apply to two State University hospitals, one county hospital and three hospitals operating as a public benefit corporation. There are approximately 200 other facilities operated by local government agencies, mostly jails and community clinics that will be affected by these regulations but that are exempt from the fees set forth in regulation.

Of the roughly 11,000 licenses and registrations currently issued under 10 NYCRR Part 16, it is estimated that approximately two-thirds constitute small business, or roughly 6,400 throughout the state. This figure does not include any hospitals, educational facilities or government operated entities.

Compliance Requirements:

This rule change will affect small businesses and local government facilities that use ionizing radiation, including healthcare facilities, colleges, and commercial services. This is a repeal and replace of the entire existing regulation. Significant changes and updates include the following:

- Radioactive material licensing is updated to incorporate federal standards by reference and to include NYS Department of Labor regulations that were previously turned over to the Department of Health.
- Radioactive materials license and x-ray equipment registration fees are increased an average of 68%, fees for reciprocity are added, and late fees are removed. Commercial license fees were converted to annual fees from triannual which will reduce the initial burden on applicants.
- The proposed rules include a requirement for accreditation and quality assurance (QA) testing on Cone-Beam CT units used on people, most of which are used in dentistry.
- QA requirements for diagnostic imaging have been updated to reflect the current technologies, in particular the replacement of film with digital imaging modalities. The regulations have been developed based on American College of Radiology (ACR) and American Association of Physicists in Medicine (AAPM) guidance documents that the Department of Health (Department) has used as a standard for facilities for the past decade.
- Definitions have been added for compatibility and clarity purposes. Other sections of the regulations have had out of date language or unclear phrasing reworded based on discussions with regulated entities and NRC staff.
- Updates require recording of high patient doses from fluoroscopy and notification of referring physician and instructions to patient.

Regulated facilities will need to become familiar with the updated rules and may need to modify their radiation safety program and quality assurance policies and procedures accordingly. Those facilities with Cone Beam CT units that are not accredited will need to do so within 18 months of the effective date of the rule.

Professional Services:

Many large facilities have in-house staff that perform quality assurance testing and operate radiation emitting technology. Smaller offices and private practices employ consultants to provide QA services and assistance in the development of policies and procedures relating to radiation safety. The QA related changes will not require significant time and the Department will provide updated guidance and references to current professional and national standards as applicable.

The Department does not expect that it will be necessary for licensees to use additional professional services for completion of applications for accreditation or to implement the quality assurance requirements other than the operators of Cone-Beam equipment who will have to develop QA plans and become accredited.

Compliance Costs:

The Cone-Beam CT accreditation will cost the registrant about $3,000 dollars for a three-year period and the Cone Beam CT QA testing will cost approximately $800 to 1,200 per year. In addition, radioactive materials license and x-ray equipment registration fees are increased an average of 68%, fees for reciprocity are added, and late fees are removed. This fee increase is needed to cover program cost as the fees have not increased since 2001. Program used the US Bureau of Labor Statistics Consumer Price Index Calculator to determine average increases from 2002 to 2023. This program is a partial cost recovery program and staff salaries, and other program operation expenses are covered through the fees. Commercial license fees were converted to annual fees from triannual which will reduce the initial burden on applicants.

Economic and Technology Feasibility

There are no capital costs or new technology required to comply with

the proposed rule. Most of the facilities affected will be dental, veterinary, and podiatric facilities and they will have a $35 increase in registration fee which is still a low-cost relative to many other states annual fees. Large hospitals, universities and other large corporate entities will see larger amounts proportional to the cost to inspect and regulate these facilities. Therefore, the proposal should be economically and technologically feasible for regulated entities.

Minimizing Adverse Impact:

Most facilities will not need a substantial amount of time to comply with these updates. Mitigating the fee increase for commercial licensees will be the fact that they only pay a 1-year fee instead of a 3-year fee. Late fees for all regulated facilities are dropped. Facilities will have 90 days to apply for accreditation and 18 months to become accredited. This will allow a facility adequate time to select the accreditation body of their choice, complete an application, and budget funds for the accreditation fee. Most users of Cone Beam CT equipment already charge patients a fee for the images made by this equipment and will be able to recoup the increased cost associated with the increased QA requirements.

Small Business and Local Government Participation:

The diagnostic quality assurance testing changes were reviewed by NYS medical and health physics societies for technical content during the past several years. The therapy regulation updates have been developed with input from radiation oncology facilities, based on current professional standards and practices. The Department of Health will provide notice of rulemaking to organizations that represent the interested parties including the dental, veterinary, podiatry, medical (MSSNY) and healthcare (HANYS) and other interested parties. In addition, the proposed regulations will be published in the State Register to provide Small Business and Local Government a review and comment period, which is an opportunity for comment and to participate in the regulatory process. Some sections of the regulations have had out of date language or unclear phrasing reworded based on discussions with regulated entities and NRC staff and many of their suggestions have been included.

For Rules That Either Establish or Modify a Violation or Penalties Associated with a Violation:

Violations that had previously been cited by 12 NCYRR Part 38 may now be cited under 10 NYCRR Part 16 as the NYS Department of Labor regulations are transcribed into Title 10 NYCRR Part 16. There are no changes to any violations or penalties, however late fees have been removed from the fee schedule and will no longer be charged.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

This rule applies uniformly throughout the state, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 44 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2020 (https://www.census.gov/quickfacts/). Approximately 17% of small health care facilities are located in rural areas.

Allegany County	Greene County	Schoharie County
Broome County	Hamilton County	Schuyler County
Cattaraugus County	Herkimer County	Seneca County
Cayuga County	Jefferson County	St. Lawrence County
Chautauqua County	Lewis County	Steuben County
Chemung County	Livingston County	Sullivan County
Chenango County	Madison County	Tioga County
Clinton County	Montgomery County	Tompkins County
Columbia County	Ontario County	Ulster County
Cortland County	Orleans County	Warren County
Delaware County	Oswego County	Washington County
Essex County	Otsego County	Wayne County
Franklin County	Putnam County	Wyoming County
Fulton County	Rensselaer County	Yates County
Genesee County	Schenectady County	

The following counties have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2020.

Albany County	Monroe County	Orange County
Dutchess County	Niagara County	Saratoga County
Erie County	Oneida County	Suffolk County
	Onondaga County	

There are just over 11,000 regulated facilities that possess and use x-ray equipment or radioactive materials. Approximately 20% are in the 44 counties defined as rural based on population and an additional 46% are in those counties defined as rural by population density. As of January 1, 2022, there are just under 7,200 facilities in rural areas. Approximately 50% of the regulated facilities are dental, 10% are veterinarians, 9% are physician's office, 8% are non-human use (academic, commercial, or industrial), 7% are hospitals, clinics or imaging centers, and the rest are a mix of podiatrists, chiropractors, and other specialty providers.

Reporting, Recordkeeping and Other Compliance Requirements and Professional Services:

There are no new reporting requirements to the State contained in the proposed regulations for most regulated facilities. However, certain medical users of fluoroscopy will have to report to the patient and maintain records of high patient exposure. This will affect hospitals and ambulatory surgery sites that perform interventional fluoroscopic procedures. No additional professional service costs are anticipated. Facilities are currently required to maintain records of quality assurance test results and accreditation documents for review by the Department's inspectors. The content of these tests is specified in sections 16.23 and 16.24 of these regulations. Compliance with the recordkeeping requirements will require only a minor incremental amount of time and effort for affected facilities.

Cost:

Fees are increased an average of 68% for all license and registration categories. Specifically, operators of Cone-Beam CT units will also have to get accredited which will cost them $3,000 for a three-year period. These units will now be subject to quality assurance testing requirements that will cost an additional $800-1,200 per year. This will affect approximately 10% of the dental practices in the state, principally oral surgeons, and other specialty practices.

Schedules for licensing and registration fees currently being assessed by the Bureau of Environmental Radiation Protection (BERP) are published under two separate Titles of the NYCRR. Title 12 NYCRR section 82.8 contains the fee schedule for radioactive materials licenses and radiation equipment registrations issued to industrial and commercial facilities formerly regulated by DOL under Industrial Code Rule number 38 (12 NYCRR 38). Title 10 NYCRR section 16.41 contains the corresponding schedule for radioactive sources regulated by the Department under 10 NYCRR Part 16. The current proposal combines these into one fee schedule to be published in 10 NYCRR § 16.41. Regulated parties would benefit from having a single fee schedule in one location for all radiation sources regulated by the Department.

The current fee schedules were established in 2001 (for the Department) and 2005 (for DOL). The costs of the Department's program have increased due to increased salary, equipment, and travel costs. In addition to these cost increases, increased security measures have been adopted requiring closer tracking and more frequent inspection by the Department of certain radiation sources that are of concern for national security reasons. The increased costs from these additional measures must be recovered through fees.

Finally, the proposed rule establishes an annual fee for reciprocity. Reciprocity is required under federal rules as it allows an entity licensed in another state to operate temporarily in New York based on their radioactive materials license in their home state. New York is currently one of only two states that does not charge a reciprocity fee (the other is Alabama). Other states' fees (including 48 other state programs) range from $100 to $1,400 with an average fee of about $900 per year.

Minimizing Adverse Impact:

Most facilities will not need to take a substantial amount of time to comply with these updates. Mitigating the fee increase for commercial licensees is the fact that they will now only pay a 1-year fee instead of a 3-year fee. In addition, late fees for all regulated facilities are dropped. Cone Beam CT facilities will have 90 days to apply for accreditation and 18 months to become accredited. This will allow a facility adequate time to select the accreditation body of their choice, complete an application and budget funds for the accreditation fee. Most users of Cone Beam CT equipment already charge patients a fee for the images made by this equipment and therefore should be able to recoup the increased costs associated with the new regulatory requirements.

Rural Area Participation:

Regulated facilities are invited to comment during the Codes and Regulations Committee meeting of the Public Health and Health Planning Council and as part of the formal public comment process. The diagnostic quality assurance testing changes were reviewed by NYS medical physics

and health physics societies for technical content during the past several years. The therapy regulation updates have been developed with input from radiation oncology facilities, based on current professional standards and practices. The majority of the changes are based on existing guidance, published federal regulations, merge DOL regulations into DOH regulations, or were clarifications and modernizations of language. DOH has communicated the nature of these updates with interested professional organizations over the past few years.

Job Impact Statement

Nature of Impact:

It is anticipated that no jobs will be adversely affected by this rule. Medical providers of diagnostic imaging and radiation therapy will need to become familiar with the new quality assurance requirements.

Categories and Numbers Affected:

There are approximately 10,000 facilities registered to use radiation producing equipment (x-ray machines), and more than 1,100 facilities authorized by license to use radioactive material. Approximately 5,500 of the x-ray facilities are dental practices.

Regions of Adverse Impact:

No areas will be adversely affected.

Minimizing Adverse Impact:

There are no alternatives to the proposed regulations. Many of these changes are required for the State to maintain compatibility with federal regulations. Non-compatibility updates reflect technological change, especially the change from film-based imaging to digital x-ray systems. The Department will revise guidance to assist all licensees, including those in rural areas, with implementation of the proposed regulations.

Self-Employment Opportunities:

The rule may have impact on some dental practices. It imposes an additional cost and a quality assurance requirement on facilities that have Cone-Beam CT units (CBCT). The Department estimates that there are between 500 and 600 practices that have CBCT units.

Department of Law

NOTICE OF EXPIRATION

The following notice has expired and cannot be reconsidered unless the Department of Law publishes a new notice of proposed rule making in the NYS *Register.*

Presumptive Cases of Gross Disparity Under the Price Gouging Law

I.D. No.	Proposed	Expiration Date
LAW-12-23-00006-P	March 22, 2023	March 21, 2024

Presumptive Unfair Leverage for Large Enterprises or Enterprises With Large Market Share Under the Price Gouging Law

I.D. No.	Proposed	Expiration Date
LAW-12-23-00007-P	March 22, 2023	March 21, 2024

Presumptive Cases of Gross Disparity for Purposes of the Price Gouging Statute

I.D. No.	Proposed	Expiration Date
LAW-12-23-00008-P	March 22, 2023	March 21, 2024

Application of Price Gouging Prohibition to Parties Within the Chain of Distribution

I.D. No.	Proposed	Expiration Date
LAW-12-23-00009-P	March 22, 2023	March 21, 2024

Application of the Price Gouging Law to Dynamic Pricing

I.D. No.	Proposed	Expiration Date
LAW-12-23-00010-P	March 22, 2023	March 21, 2024

Presumptive Cases of Unfair Leverage for Purposes of the Price Gouging Law

I.D. No.	Proposed	Expiration Date
LAW-12-23-00011-P	March 22, 2023	March 21, 2024

Costs not Within the Control of the Defendant for Purposes of the Price Gouging Law

I.D. No.	Proposed	Expiration Date
LAW-12-23-00012-P	March 22, 2023	March 21, 2024

Office of Mental Health

PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED

Prior Approval Review Process

I.D. No. OMH-15-24-00002-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed Action: Repeal of Part 551; addition of new Part 551 to Title 14 NYCRR.

Statutory authority: Mental Hygiene Law, sections 7.07, 7.09 and 31.04

Subject: Prior Approval Review Process.

Purpose: To update the Prior Approval Review Process.

Substance of proposed rule (Full text is posted at the following State website: https://omh.ny.gov/omhweb/policy_and_regulations/): In addition to technical updates and eliminating outdated terminology by repealing and replacing Part 551, the Proposed Rule provides as follows:

551.1 Background and intent. Updates language from the repealed Part 551 to establish minimum standards for seeking an operating certificate from the Office of Mental Health (office) which will meet appropriate criteria for quality, safety and fiscal viability and to support the efforts of local governmental units in the process of planning and funding local systems of mental health service. The language expedites the review of projects that are in conformance with the Statewide Plan and establishes an efficient and timely process for the initial licensure of a program.

551.2 Legal base. No substantive changes from the repealed Part 551.

551.3 Applicability. Updates language from the repealed Part 551 to clarify applicability to any existing or proposed limited liability company, corporation or public or private agency proposing a project and that such does not apply to family care home providers or programs not required to obtain an operating certificate.

551.4 Definitions. Removes outdated language and updates definitions from the repealed Part 551 for Capacity and Alteration to a capital project. Updates the definition of caseload to census. Removes an outdated definition for governing authority, and clarifies the definition of inpatient program, licensed housing and outpatient program.

551.5 Project planning and consultation. Clarifies that the applicant may be required to obtain a Memorandum of Understanding (MOU) whenever a project is physically hosted by another service provider in the same building. Clarifies that EZ-PAR applicants will be required to obtain a letter of support from the local governmental unit of the county where the program is to be established or located and that the applicant will consult with designated staff of the office prior to the submission of an E-Z PAR or Comprehensive PAR application.

551.6 Project subject to prior approval review. Clarifies that all projects subject to prior approval review will be classified as a comprehensive, E-Z PAR, or administrative action project and where a project consists of two or more components that fall within separate classifications, the entire project will be reviewed under the classification that is determined to be most appropriate by the office. Clarifies the commissioner's authority to charge a review fee to applicants for projects in accordance with a published fee schedule. Provides that a change of sponsor of a program licensed by the office, to a sponsor that does not currently operate a program licensed by the office or has been licensed for less than twelve months will be a comprehensive review project and where the agency ceasing operation of the program is separate from the agency that is assuming operation, an E-Z PAR to close is required of the agency ceasing operation. Projects classified as E-Z PAR review projects are clarified to include outpatient program projects submitted by an applicant who currently operates one or more programs that are currently licensed by the office, including the expansion or reduction of a Mental Health Outpatient Treatment and Rehabilitative Services (MHOTRS) program that results in a staffing change greater than 5.5 full-time equivalent staff; licensed housing projects submitted by an applicant who currently operates a program which has been licensed by the office, including the relocation of licensed housing, excluding licensed apartment treatment units; all capital projects unless otherwise determined by the office and will require a site visit at the completion of the project; a project proposing either a change in ownership of the stock of a business corporation or membership certificates of a