in the Notice of Proposed Rule Making, remain valid and do not need to be amended.

Initial Review of Rule

As a rule that requires a RFA, RAFA or JIS, this rule will be initially reviewed in the calendar year 2025, which is no later than the 3rd year after the year in which this rule is being adopted.

Assessment of Public Comment

A Proposed Rulemaking was released for public review on October 27, 2021 with a 60 day comment period extending through December 26, 2021. Public comment was solicited through:

- a posting of the statewide public comment period in the Environmental Notice Bulletin (ENB),
- a DEC press release distributed statewide, and
- two announcements distributed to all subscribers to the DEC Delivers Fishing Line newsletter [approximately 150,000 recipients] on October 29, 2021, and December 17, 2021.

A total of 69 public comments were received. Fifty-five comments were received on each of the three primary proposals (statewide sunfish, statewide crappie, and Big Panfish Initiative (BPI) sunfish), most of which were in support. The statewide sunfish regulation proposal received 50 comments in support and 5 in opposition, the statewide crappie proposal received 44 comments in support and 11 in opposition, and the BPI sunfish proposal received 41 comments in support and 14 in opposition. Other comments were specific to individual BPI waters, suggested other regulatory options, did not provide an opinion on the proposals, or did not apply to the proposals. Of the few comments that were specific to individual BPI waters, support was expressed for Cazenovia Lake (1 comment), Honeoye Lake (2 comments) and Silver Lake (2 comments), and opposition was expressed for Otisco Lake (1 comment) and Silver Lake (2 comments).

Comments were grouped into 8 themes. Responses to those themes are included below. Comments in support of the proposals are not included in this assessment.

Comment #1: The proposed statewide 10 inch minimum size limit for crappie is too restrictive and will make it very difficult to harvest a worthwhile number.

Response: The proposed increase in the statewide regulation from 9 inches to 10 inches is intended to improve the size quality of crappie for anglers in waters that are capable of producing fish of that size. Harvest in unproductive waters where crappies are typically small or stunted is likely limited regardless of what the minimum size limit is because few fish can reach sizes desirable to anglers.

Comment #2: Further limiting harvest of these panfish will be counterproductive and result in overabundant, stunted populations.

Response: A stunted fish population is one that is overpopulated with a subsequent reduced growth rate and high natural mortality, resulting in few fish reaching sizes that are desirable to anglers. It is generally caused by excessive reproduction, insufficient predation on juvenile or otherwise small fish, limited resources, or any combination of these factors. As such, stunting is more likely to occur in waters that are not capable of producing good numbers of quality sized fish and angler harvest is likely to be minimal in these waters regardless of the daily limit. Waters with the potential for producing quality sized fish could benefit from more conservative regulations as angler harvest is generally the biggest driver of adult mortality and size structure in these systems.

Comment #3: The proposed BPI sunfish 8 inch minimum size limit will cause anglers to release some smaller fish that are likely to die from hooking trauma that they would have otherwise kept.

Response: It is recognized that some of these smaller sunfish with hooking trauma may need to be released. The potential degree and severity of this is unknown, but it is not expected to have a major negative impact on anglers or the resource. The Department feels that the potential benefits of the 8 inch minimum size limit to the sunfish fishery outweigh the risk. Anglers will have opportunities to provide feedback on this and other issues related to the BPI through planned angler surveys.

Comment #4: The BPI regulations, or other more conservative regulations, should be more widely applied, including reducing the possession limit for crappie to 15/day in sunfish BPI waters and further protecting the largest sunfish.

Response: The proposals in the draft plan were developed with the recognition that while sunfish and crappie anglers have diverse interests and behaviors, these fisheries are generally harvest-based. It was important to develop regulations that were not only more conservative, but were simple and easy to follow, were acceptable to anglers, and made biological sense without unduly diminishing fishing opportunity. More conservative regulations may be considered in the future based on the outcomes of the BPI experiment.

Comment #5: The BPI proposal is unnecessary, adds to already complex fishing regulations, and will discourage fishing.

Response: The BPI was proposed as a 5-year experimental program for relatively few waters across the state that have potential to provide unique fisheries for large sunfish. This proposal aims to creatively develop more diverse sunfish fishing opportunities by taking advantage of the ecological capacity of select lakes to provide a special fishing experience. While this would add to the suite of fishing regulations, the Bureau believes that these waters have the potential to become destination fisheries for anglers who seek out larger sunfish.

Comment #6: There should be a prohibition on the commercial sale of sunfish.

Response: Commercial sale of panfish has been a longstanding concern because it increases the motivation to harvest large numbers of fish. However, attempts to legislatively prohibit the sale of panfish have failed in the past and moving forward with such a dramatic change would risk making progress on other practical and obtainable conservation measures. The statewide sunfish regulation proposal is designed to moderate situations where overharvest may occur.

Comment #7: What data and information were used to justify these proposals?

Response: The BPI program was conceptually based on available and relevant science and similar, successful, management programs in the Midwest that were based on that same science. BPI lakes were selected based on information derived from the Statewide Database, the statewide angler survey, and input from Regional staff who are familiar with and manage these waters. Criteria for selecting those waters were largely based on criteria identified in the literature that were related to positive size structure changes due to more conservative regulations.

Statewide regulations were based on the recognition that a more conservative approach was needed in light of new fishing technology and other advancements, and feedback from sunfish anglers indicating support for that type of approach.

Comment #8: A better approach would be to increase enforcement of current regulations and/or increase access to panfish fisheries.

Response: These are important issues that the Department will continue to work on and advance in the best interest of our fisheries resources.

Department of Health

NOTICE OF ADOPTION

Managed Care Organizations (MCOs)

I.D. No. HLT-22-21-00009-A
Filing No. 130
Filing Date: 2022-03-03
Effective Date: 2022-03-23

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

Action taken: Amendment of section 98-1.11(e) of Title 10 NYCRR.

Statutory authority: Public Health Law, section 4403(2)

Subject: Managed Care Organizations (MCOs).

Purpose: To maintain the contingent reserve requirement at 7.25% through 2022 applied to Medicaid Managed Care, HIV SNP and HARP programs.

Text or summary was published in the June 2, 2021 issue of the Register, I.D. No. HLT-22-21-00009-P.

Final rule as compared with last published rule: No changes.

Text of 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

Initial Review of Rule

As a rule that does not require a RFA, RAFA or JIS, this rule will be initially reviewed in the calendar year 2027, which is no later than the 5th year after the year in which this rule is being adopted.

Assessment of Public Comment

The agency received no public comment.

PROPOSED RULE MAKING
NO HEARING(S) SCHEDULED

Clinical Laboratories and Blood Banks

I.D. No. HLT-12-22-00001-P

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

Proposed Action: Amendment of Subpart 58-1 of Title 10 NYCRR.

Statutory authority: Public Health Law, section 576

Subject: Clinical Laboratories and Blood Banks.

Purpose: To allow for remote supervision and updates to provide concordance with NYSED law for qualifications of technical personnel.

Substance of proposed rule (Full text is posted at the following State website: https://regs.health.ny.gov/regulations/proposed-rule-making): Part 58-1 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) regulates the permitting and operation of clinical laboratories and blood banks. An entity operating a clinical laboratory or blood bank located in New York State, or accepting specimens from a person or entity in New York State, is required to hold a permit issued by the New York State Department of Health (Department). The proposed amendments to sections 58-1.1 through 58-1.5 revise several aspects of the current regulation.

Section 58-1.1 specifically defines the permitting process for clinical laboratories, including criteria for a permit, allowable categories of testing, and the process for obtaining provisional permits. Amendments to paragraph 58-1.1(a)(1) clarify that testing or procedures performed under a permit must be approved by the U.S. Food and Drug Administration or the Department. Paragraph 58-1.1(a)(2) is amended to define conditions for permit denial and to define allowable owners. Subdivision 58-1.1(d) is amended to better define the conditions under which provisional permits can be issued. New subdivision 58-1.1(e) is added to define the process for voiding a permit, consistent with Public Health Law (PHL) § 575(6). New subdivision 58-1.1(f) defines the process for issuance of a "single use permit," which would allow access to testing on a patient or test specific basis under certain circumstances, such as a during a declared state disaster emergency.

Section 58-1.2 sets forth the required availability of the laboratory director to the clinical laboratory or blood bank and his or her responsibilities. Amendments to subdivisions 58-1.2(a)-(b) establish the title of "sole assistant director," a person responsible for one or more categories on the laboratory or blood bank permit for which the laboratory director does not hold a Certificate of Qualification. The sole assistant director would be treated as the laboratory director for those categories. Amendments to subdivision 58-1.2(b) also allow a laboratory director to serve at five different clinical laboratories or blood banks, or any combination thereof. Amendments to subdivision 58-1.2(c) set forth expectations for the onsite presence of the director and sole assistant director while also providing for exceptions.

Revisions in section 58-1.2 also include a definition of "regular part time hours," to allow onsite supervision at a reduced frequency. Subdivisions 58-1.2(d)-(e) define the responsibilities of laboratory directors and sole assistant directors. Subdivisions 58-1.2(f)-(g) set forth expectations for coverage and notification when the laboratory director's or sole assistant director's employment is terminated. Finally, new subdivision 58-1.2(g) defines the consequences of an extended absence of a director or sole assistant director when a new individual is not identified as a replacement. The proposed revisions now define that absences of greater than 60 days require prior notification and approval by the Department.

Section 58-1.3 sets forth the roles and responsibilities of a clinical laboratory supervisor. Amendments to section 58-1.3 expand supervisor titles from just clinical laboratories to blood banks, as per PHL, and allow for supervisors to oversee "procedures" in addition to "tests," as appropriate for blood banks. Amendments to subdivision 58-1.3(d) provide criteria for allowing an exception to the requirement to have a supervisor onsite during all hours of laboratory testing. Subsection 58-1.3(e) is amended to expand the allowable areas for cytotechnologist supervision in accordance with their scope of practice as interpreted by the New York State Education Department (NYSED).

Section 58-1.4 defines the qualifications of a clinical laboratory supervisor, and section 58-1.5 defines the duties and qualifications of clinical laboratory technical staff. Amendments to section 58-1.4 define "acceptable laboratory," by describing the experience required for qualification of supervisors and staff, reducing the number of years of experience in such "acceptable laboratories" required to qualify as a supervisor, and expanding the criteria to allow certificate of qualification holders to serve as supervisors. Sections 58-1.4 and 58-1.5 are also amended to revise the duties and responsibilities of additional laboratory staff, as well as respiratory therapists, and to revise the qualifications for such staff to conform to NYSED licensure requirements. These amendments also allow supervisors and staff working in laboratories outside of New York State to qualify under the appropriate titles if they meet Department requirements or are licensed in their state or other jurisdiction. Deletions from these sections remove outdated language that is no longer applicable, simplifying the regulation overall.

A new section 58-1.14 is added clarifying reporting requirements for results of laboratory testing for certain communicable diseases. The section requires the Commissioner to designate those tests for communicable disease that require prompt action, and to make available a list of such diseases on the State Department of Health website. It also requires clinical laboratories to immediately report positive test results for communicable diseases identified as requiring prompt attention, in a manner and format identified by the Commissioner. Finally, the new section requires clinical laboratories to report all test results, including negative and indeterminate results, for communicable diseases identified as requiring prompt attention, via the Electronic Clinical Laboratory Reporting System (ECLRS).

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:

Public Health Law (PHL) § 576 authorizes the New York State Department of Health (Department) to promulgate regulations to effectuate the provisions and purposes of Title V of Article 5 of the PHL, relating to the issuance of permits and the requirements for operating a clinical laboratory or blood bank.

Legislative Objectives:

Title V of Article 5 of the PHL is intended to promote the public health, safety, and welfare by requiring the permitting of clinical laboratories and blood banks and by requiring that the performance of tests and procedures employed by clinical laboratories and blood banks meet minimum standards accepted and approved by the Department.

Needs and Benefits:

Amendments to section 58-1.1 clarify that tests or procedures performed by a clinical laboratory or blood bank must be approved by the Food and Drug Administration (FDA) or by the Department; define allowable owners and laboratory directors of clinical laboratories and blood banks; specify conditions for permit denial; and better describe the conditions under which provisional permits can be issued. These amendments are beneficial to the Department and to regulated parties because they provide clarity to the permitting process. Further, during the COVID-19 public health emergency, the need for a streamlined process to issue provisional permits became evident to allow the department to quickly approve laboratories located in New York to initiate COVID-19 testing. For example, the current regulation specifically prohibits the issuance of a provisional permit in Virology, the category under which diagnostic COVID-19 testing is performed. By removing this language and revising other criteria for provisional permit issuance, the Department will be better positioned to respond more rapidly in the event of future novel communicable disease outbreaks. Additionally, subdivision 58-1.1(e) codifies the process for voiding a permit.

The introduction of a "single use permit" will allow access to testing on a patient- or test-specific basis, when such testing is medically necessary, needed as part of a clinical trial, or as part of a declared state of emergency. Single-use permits are beneficial to the public health by allowing testing to be performed by laboratories that do not hold a New York State clinical laboratory or blood bank permit, but which can nevertheless offer important services to patients. In addition to being able to be used during a pandemic, single-use permits will allow testing for extremely rare disorders or where testing capacity of New York State permitted laboratories is limited and additional support is needed to meet testing demands.

Amendments to section 58-1.2 add the term "sole assistant director," which is a person responsible for one or more categories on the laboratory permit for which the laboratory director does not hold a certificate of qualification. Sole assistant directors will be treated as laboratory directors for those categories. Amendments to this section will also increase the number of allowable directorships an individual may hold and establish requirements for the onsite presence of laboratory directors, notification of laboratory director changes and notification of laboratory director absences. These changes provide flexibility and reduce the regulatory burden on clinical laboratories.