RULES AND REGULATIONS

Title 25—ENVIRONMENTAL PROTECTION

ENVIRONMENTAL QUALITY BOARD

[25 PA. CODE CH. 109]

Safe Drinking Water PFAS MCL Rule

The Environmental Quality Board (Board) amends Chapter 109 (relating to safe drinking water) to read as set forth in Annex A. This final-form rulemaking will improve public health protection by setting maximum contaminant level goals (MCLG) and maximum contaminant levels (MCL) for two per- and polyfluoroalkyl substances (PFAS)—perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS).

PFAS are considered emerging contaminants because research is ongoing to better understand the potential impacts PFAS pose to human and animal health and the environment. PFAS are potentially linked to a number of adverse health effects, including high cholesterol, developmental effects including low birth weight, liver toxicity, decreased immune response, thyroid disease, kidney disease, ulcerative colitis and certain cancers, including testicular cancer and kidney cancer.

This final-form rulemaking will protect public health by setting State MCLs for contaminants in drinking water that are currently unregulated at the Federal level. With this final-form rulemaking, the Commonwealth has moved ahead of the United States Environmental Protection Agency (EPA) in addressing PFOA and PFOS in drinking water and joins a small group of states that have set regulatory limits for select PFAS in drinking water. Currently, seven states have set MCLs or other regulatory limits for one or more PFAS—Massachusetts, Michigan, New Hampshire, New Jersey, New York, Vermont and Washington.

Safe drinking water is vital to maintaining healthy and sustainable communities. Proactively addressing PFOA and PFOS contamination in drinking water can reduce the incidence of illness and reduce health care costs. Although the EPA has started the process of setting more stringent standards for PFOA and PFOS in drinking water, that process is expected to take years to complete. For that reason, these more protective standards for this Commonwealth will better protect the health of residents in this Commonwealth. Proper investment in public water system infrastructure and operations helps ensure a continuous supply of safe drinking water, enables communities to plan and build future capacity for economic growth, and ensures their long-term sustainability for years to come.

The PFOA and PFOS MCLs will apply to all 3,117 community, nontransient noncommunity, bottled, vended, retail and bulk water systems in this Commonwealth. Of these, 1,905 are community water systems, serving a combined population of approximately 11.4 million residents in this Commonwealth; another 1,096 are nontransient noncommunity water systems serving approximately 507,000 persons.

This final-form rulemaking also includes minor amendments to address incorrect cross-references and citations, delete duplicated text and update language to be consistent with revisions made in the 2018 General Update of the Chapter 109 regulations. These minor amendments are a codification of existing practices and will have no change from current practice.

This final-form rulemaking was adopted by the Board at its meeting of October 12, 2022.

A. *Effective Date*

This final-form rulemaking will be effective upon publication in the *Pennsylvania Bulletin*. Initial compliance monitoring for community and nontransient noncommunity water systems serving a population of greater than 350 persons and all bottled, vended, retail and bulk hauling water systems begins January 1, 2024; initial monitoring for community and nontransient noncommunity water systems serving a population of less than or equal to 350 persons begins January 1, 2025.

B. *Contact Persons*

For further information, contact David Mittner, Acting Director, Bureau of Safe Drinking Water, P.O. Box 8467, Rachel Carson State Office Building, Harrisburg, PA 17105-8467, (717) 783-6865; or Leda J. Lacomba, Assistant Counsel, Bureau of Regulatory Counsel, P.O. Box 8464, Rachel Carson State Office Building, Harrisburg, PA 17105-8464, (717) 787-7060. Persons with a disability may use the Pennsylvania Hamilton Relay Service at (800) 654-5984 (TDD users) or (800) 654-5988 (voice users). This final-form rulemaking is available on the Department of Environmental Protection's (Department) web site at www.dep.pa.gov (select "Public Participation," then "Environmental Quality Board" and then navigate to the Board meeting of October 12, 2022).

C. *Statutory Authority*

This final-form rulemaking is being made under the authority of section 4 of the Pennsylvania Safe Drinking Water Act (act) (35 P.S. § 721.4), which grants the Board the authority to adopt rules and regulations governing the provision of drinking water to the public, and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20), which authorizes the Board to promulgate rules and regulations necessary for the performance of the work of the Department.

D. *Background and Purpose*

PFAS are a large class of man-made synthetic chemicals that were created in the 1930s and 1940s for use in many industrial and manufacturing applications. It is estimated that the PFAS family includes more than 6,000 chemical compounds. PFAS have been widely used for their unique properties that make products repel water, grease and stains, reduce friction and resist heat. PFAS are found in industrial and consumer products such as clothing, carpeting, upholstery, food packaging, non-stick cookware, fire-fighting foams, personal care products, paints, adhesives, metal plating, wire manufacturing and many other uses. Because of their unique chemical structure, PFAS readily dissolve in water and are mobile, are highly persistent in the environment and bioaccumulate in living organisms over time.

Decades of widespread use of products containing PFAS has resulted in elevated levels of environmental pollution and exposure in some areas of the State. PFAS remain in the environment and cycle through various media (air, water, soil) depending on how and where the substances were released. The primary means of distribution of PFAS throughout the environment has been though the air, water, biosolids, food, landfill leachate and fire-fighting activities. For a diagram showing the PFAS cycle and its exposure pathways, refer to the Department's PFAS webpage at www.dep.pa.gov/Citizens/My-Water/drinking_water/PFAS/Pages/DEP-Involvement.aspx. As noted previously, PFAS are potentially linked to a number of adverse health effects, including high cholesterol, developmental effects including low birth weight, liver toxicity, decreased immune response, thyroid disease, kidney disease, ulcerative colitis and certain cancers, including testicular cancer and kidney cancer.

The Department's Safe Drinking Water Program first became aware of PFAS as emerging contaminants in 2013 when the EPA included six PFAS in its Third Unregulated Contaminant Monitoring Rule (UCMR 3). The six PFAS included in UCMR 3 monitoring are PFOA, PFOS, perfluorononanoic acid (PFNA), perfluorohexanesulfonic acid (PFHxS), perfluoroheptanoic acid (PFHpA) and perfluorobutanesulfonic acid (PFBS). The UCMR rules are Federal direct-implementation rules that are updated every 5 years to require monitoring for up to 30 unregulated contaminants to generate National occurrence data and inform the Federal regulatory determination process. Public water systems (PWS) serving more than 10,000 people and a select number of smaller PWSs were required to monitor for PFAS and other contaminants during 2013—2015 for UCMR 3. In this Commonwealth, a total of 175 systems conducted monitoring; of these systems, PFAS was detected at six systems above the 2009 Provisional Health Advisory Levels (HAL) for PFOA and PFOS of 400 nanograms per liter (ng/L) or parts per trillion (ppt) and 200 ng/L, respectively. The Department worked closely with the EPA and the PWSs to address the elevated levels of PFAS found during the UCMR 3 monitoring.

In 2016, the Department began implementing the EPA's 2016 Final Combined Lifetime HAL of 70 ng/L for PFOA and PFOS using existing authority under the act and Chapter 109 regulations. PWSs that exceed the 2016 EPA HAL are required to conduct follow-up and corrective actions to protect public health, including the following actions:

- One-hour reporting of sample results to the Department to ensure timely consultation and oversight regarding investigative and corrective actions (§ 109.701(a)(3)(iii) (relating to reporting and recordkeeping)),
- Collection of confirmation samples (§ 109.302 (relating to special monitoring requirements)),
- Issuance of Tier 2 Public Notice to consumers (§ 109.409 (relating to Tier 2 public notice—categories, timing and delivery of notice)),
- Quarterly monitoring at the entry point (EP) to track levels of contamination (§ 109.302), and
- If levels continue to exceed the HAL, taking additional actions as needed to protect public health such as taking contaminated sources off-line or installing treatment (§ 109.4 (relating to general requirements)).

PFAS Action Team

In the absence of Federal action to address PFAS, Governor Tom Wolf signed Executive Order 2018-08 (EO) on September 19, 2018, published at 48 Pa.B. 6382 (October 6, 2018). The EO created the PFAS Action Team, a multi-agency group tasked with, among other things, developing a comprehensive response to identify and eliminate sources of contamination, ensure drinking water is safe, manage environmental contamination, review gaps in data and oversight authority and recommend actions to address those gaps. The PFAS Action Team released its Initial Report in December of 2019 to the Department's PFAS webpage at www.dep.pa.gov/pfas. The report includes information about PFAS, challenges associated with managing contamination, actions taken to date and recommendations for future actions. Recommendations include additional funding for communities dealing with PFAS contamination and strengthened statutory authorities to adequately address PFAS.

In 2019, the Department's Safe Drinking Water Program moved forward with two key projects to advance its knowledge of PFAS—the PFAS Sampling Plan and PFAS Toxicology Services Contract.

PFAS Sampling Plan

The PFAS Sampling Plan was developed and posted to the Department's PFAS webpage in April of 2019. The plan prioritized PWS sites for PFAS sampling to generate Statewide occurrence data. Several factors were considered in developing the targeted plan, including:

- Identification of "potential sources of PFAS contamination" (PSOC) based on a literature review,
- Identification of PWS sources located within 0.5 to 0.75 miles from PSOCs, and
- Selection of PWS sources to serve as a control or baseline group.

The selection process involved a combination of spatial analysis and programmatic review. The spatial analysis included the creation of a Geographic Information System (GIS) project using ArcMap 10.4.1 that focused on PWS source locations and information about PSOCs. The sampling pool was prioritized based on relative risk and included community water systems and nontransient noncommunity water systems. To prioritize sampling, the selection process included an assessment of the potential risk from nearby PSOCs. Several layers containing locational and other information specific to PSOCs were created or otherwise included in the GIS. These layers include the following industries and land uses:

- Military bases
- Fire training schools/sites
- Airports
- Landfills
- Manufacturing facilities (apparel, chemicals, electronics, fabricated metal, paper products, textiles and leather, upholstered furniture)
- State Hazardous Sites Cleanup Act sites, the EPA Superfund sites and other known PFAS-contamination sites

The Sampling Plan includes details about the sources of GIS data and multiple maps that indicate the locations and prevalence of the PSOCs and the locations of the targeted and baseline sampling sites.

Based on the compilation of PSOCs, PWS sources were selected that are located within 0.5 to 0.75 miles of a

PSOC. The initial sampling pool included 493 PWS sources. The sampling pool contained a mix of PWS types and sizes and provided a good spatial distribution across the State. Based on available funding of $500,000, the Department proposed sampling at 360 targeted and 40 baseline EP sites. Baseline sources are located in a HUC-12 watershed (a watershed assigned a 12-digit hydrologic unit code, or HUC, by the United StatesGeological Survey) with at least 75% forested land and at least 5 miles from a PSOC. Ultimately, samples were collected from 412 EPs including 372 targeted sites and 40 baseline sites. Note that an EP to the distribution system may include water from more than one source of supply.

Sampling and analysis by EPA Method 537.1 was completed at the end of March 2021, and the final sample results were posted to the Department's PFAS webpage in June 2021. Table 1 includes a summary of the results from the PFAS Sampling Plan for the same six PFAS that were sampled under UCMR 3.

Table 1. Summary of PFAS Sampling Plan results. Full results available at www.dep.pa.gov/pfas.

Summary of PFAS Sampling Plan Results							
	PFOA	*PFOS*	*PFNA*	*PFHxS*	*PFHpA*	*PFBS*	*Units*
Total No. Samples	412	412	412	412	412	412	—
Average	2.0	2.5	0.4	1.4	0.7	1.1	ng/L
Median	0 (ND)	0 (ND)	0 (ND)	0 (ND)	0 (ND)	0 (ND)	ng/L
Minimum	0 (ND)	0 (ND)	0 (ND)	0 (ND)	0 (ND)	0 (ND)	ng/L
Maximum	59.6	187.1	18.1	140.0	32.6	64.0	ng/L
No. and % of Detects	*112 (27%)*	*103 (25%)*	*23 (6%)*	*52 (13%)*	*49 (12%)*	*66 (16%)*	—
Avg Detect Value	*7.5*	*9.9*	*7.2*	*10.9*	*6.1*	*7.0*	*ng/L*
Med Detect Value	5.3	6.5	5.6	4.5	4.5	4.2	ng/L
Min Detect Value	1.7	1.8	1.8	1.9	1.8	1.7	ng/L
Max Detect Value	59.6	187.1	18.1	140.0	32.6	64.0	ng/L

For example, of the 412 samples analyzed for PFOA, 112 (27%) resulted in detectable concentrations of PFOA. The remaining 300 samples resulted in no detectable concentrations of PFOA. For the 112 samples in which PFOA was detected, the average detected value was 7.5 ng/L, the median detected value was 5.3 ng/L, the minimum detected value was 1.7 ng/L, and the maximum detected value was 59.6 ng/L.

At the sampling sites with detections, eight of the 18 PFAS included in EPA Method 537.1 were detected. The eight PFAS that were detected are: PFOA, PFOS, PFNA, PFHxS, PFHpA, PFBS, perfluorohexanoic acid and perfluoroundecanoic acid. Of the PFAS detected, PFOA and PFOS were most common, detected at 112 (or 27%) and 103 (or 25%) sites, respectively. Of the 412 total samples, two of the results were above the 2016 EPA HAL of 70 ng/L for the combined concentrations of PFOA and PFOS. Results were non-detect (ND) at all 412 sites for the other ten PFAS that were tested.

Additionally, there are 23 results with detections from UCMR 3 monitoring that were also included in the occurrence data evaluation. Because the reporting limits used for UCMR 3 monitoring (40 ng/L for PFOA and 20 ng/L for PFOS) were much higher than current reporting limits (which are generally below 5 ng/L), the Department did not include UCMR 3 data that was below the UCMR 3 reporting limits.

Therefore, the Department used results from a total of 435 sampling sites in the evaluation of occurrence data.

PFAS toxicology services contract

In December 2019, the Department's Safe Drinking Water Program executed a toxicology services contract with Drexel University to review other Federal and State agency work on MCLs; independently review the data, science and studies; and develop recommended MCLGs for select PFAS. MCLGs are nonenforceable, developed solely based on health effects, and do not take into consideration other factors, such as technical limitations and cost. MCLGs are the starting point for determining MCLs.

Deliverables were developed by the Drexel PFAS Advisory Group (DPAG)—a multidisciplinary team of experts in toxicology, epidemiology, and drinking water standards and risk assessment—and were completed in January 2021. These deliverables are the "Drexel PFAS Workbook" and "MCLG Drinking Water Recommendations for PFAS in the Commonwealth of PA" (MCLG Report), available at the following links: Workbook, https://files.dep.state.pa.us/PublicParticipation/Public%20Participation%20Center/PubPartCenterPortalFiles/Environmental%20Quality%20Board/2021/June%2015/03_PFAS%20Petition/01b_App%202%20Drexel%20PFAS%20Workbook%20January%202021.pdf and Report, https://files.dep.state.pa.us/PublicParticipation/Public%20Participation%20Center/PubPartCenterPortalFiles/Environmental%20Quality%20Board/2021/June%2015/03_PFAS%20Petition/01a_App%201%20Drexel%20PFAS%20Report%20January%202021.pdf.

The DPAG reviewed pertinent literature and work across the country and independently developed recommended MCLGs based on non-cancer endpoints. In the "Drexel PFAS Workbook," the DPAG explains how threshold levels (such as advisory levels, MCLGs, MCLs) are generally determined, although each state's process can vary. The MCLG Report discusses relevant inputs and includes a summary table for each PFAS that documents the development of the recommended MCLG. Table 2 includes the Reference Dose and recommended Chronic Non-Cancer MCLG for each PFAS that was reviewed.

Table 2. DPAG Reference Dose and Recommended Chronic Non-Cancer MCLGs.

DPAG Reference Dose and Recommended Chronic Non-Cancer MCLGs		
PFAS	*Reference Dose (ng/kg/day)*	*MCLG (ng/L or ppt)*
PFOA	3.9	8
PFOS	3.1	14
PFNA	2.2	6
PFHxS	4.0	20
PFHpA	None derived*	8
PFBS	39	55
GenX (HFPO-DA)	75	108

*Reference dose was not derived due to a lack of evidence on its toxicity. Recommended MCLG is based on its chemical structure.

As the DPAG explains in its MCLG Report, it "reviewed a number of recommendations made by EPA and State agencies that chose to create a summative approach to PFAS, combining multiple minimal risk levels or advisory levels into one cumulative drinking water value. No clear consensus exists on this approach and the use of the summative approach was clearly designed to be a shortcut based on a presumption that the agents all have similar health effects and end points. While this approach may work for other toxins such as dioxins, furans, and coplanar polychlorinated biphenols, it does not appear to be based on evidence available for PFAS. The DPAG therefore committed early in the process to developing an individual MCLG for each of the requested PFAS." (DPAG, January 2021)

The DPAG further describes in the MCLG Report that "For each of the PFAS studied, the DPAG identified points of departure (POD) and rationale for selection from risk assessments published by other States, the EPA and the Agency for Toxic Substances and Disease Registry (ATSDR). The DPAG then assessed the underlying critical studies driving the selection of the POD. Every effort was made to use the experience and published findings from other agencies and build and refine on these as much as possible into a best practice approach." (DPAG, January 2021)

The PFAS Toxicology Services Contract was renewed in 2021 so that the DPAG could provide additional detail on the health benefits and cost savings achieved by these MCLs. Section G of this preamble presents information on the costs and benefits of this final-form rulemaking.

MCL rulemaking process

The Department followed a rigorous process when setting the MCLs in this final-form rulemaking. An MCL rulemaking must be based on available data, studies and science, and must consider all factors as required by the Federal Safe Drinking Water Act (Federal Act) (42 U.S.C.A. §§ 300f—300j-27) and the Commonwealth's Regulatory Review Act (RRA), (71 P.S. §§ 745.1—745.14). Among other things, the Department must consider the following:

- Health effects,
- Occurrence data,
- Technical limitations such as available analytical methods and detection and reporting limits,
- Treatability of the contaminant and available treatment technologies, and
- Costs and benefits (71 P.S. § 745.5b).

In addition to State requirements, the Department needs to consult the Federal Act and its implementing regulations. See 42 U.S.C.A. §§ 300f—300j-9; see also 40 CFR Parts 141, 142 and 143 (relating to National primary drinking water regulations; National primary drinking water regulations implementation; and other safe drinking water act regulations). The EPA explains how the agency sets standards at www.epa.gov/sdwa/how-epa-regulates-drinking-water-contaminants. In establishing the MCLs in this final-form rulemaking, the Department was informed by the EPA's procedure to establish an MCL. It is important to understand the process of setting an MCL because similar criteria are required of the Department under the RRA. In addition, to retain primacy for implementing the Federal Act in this Commonwealth, the Department's standard setting process must be at least as stringent as the Federal process.

After reviewing health effects data, the EPA sets an MCLG. MCLGs are nonenforceable public health goals. MCLGs consider only public health and not the limits of detection and treatment technology effectiveness. Therefore, MCLGs sometimes are set at levels which water systems cannot meet because of technical limitations.

Once the MCLG is determined, the EPA sets an enforceable standard. In most cases, the standard is an MCL. The MCL is set as close to the MCLG as feasible. Taking cost into consideration, the EPA must determine the feasible MCL.

As a part of the rule analysis, the Federal Act requires the EPA to prepare a health risk reduction and cost analysis in support of any standard. The EPA must analyze the quantifiable and nonquantifiable benefits that are likely to occur as the result of compliance with the proposed standard. The EPA must also analyze increased costs that will result from the proposed drinking water standard. In addition, the EPA must consider incremental costs and benefits associated with the proposed alternative MCL values. Where the benefits of a new MCL do not justify the costs, the EPA may adjust the MCL to a level that maximizes health risk reduction benefits at a cost that is justified by the benefits.

This final-form rulemaking sets new MCLGs and MCLs for PFOA and PFOS. The rulemaking also establishes the provisions necessary to comply with the MCLs, including requirements for monitoring and reporting, public notification, consumer confidence reports, best available treatment technologies and analytical requirements.

PFOA—DPAG development of MCLG

After a literature search and a review of the available evidence and recommendations from various agencies, the DPAG developed an MCLG recommendation for PFOA of 8 ng/L or ppt based on non-cancer endpoints. The DPAG determined that the most relevant inputs were from the EPA, ATSDR, Minnesota Department of Health (MDH), New Jersey Department of Environmental Protection and Michigan Department of Health and Human Services (MDHHS).

The DPAG selected Koskela, et al. (2016) and Onishchenko, et al. (2011) as the critical studies, which identified developmental effects (for example, neurobehavioral and skeletal) as critical. The DPAG adopted

the ATSDR's estimated Point of Departure (POD) of 8.29 mg/L. The DPAG followed the approaches used by MDHHS, MDH and ATSDR to select and determine the Human Equivalent Dose (HED), Uncertainty Factors (UF), Reference Dose (RfD), Relative Source Contribution (RSC), and recommended MCLG. Table 3 provides a summary of the DPAG's derivation of the MCLG for PFOA.

Table 3. DPAG Derivation of PFOA MCLG (DPAG, January 2021)

PFOA	
Drexel PFAS Advisory Group (DPAG) 2021	
Dose Response Modeling Method	LOAEL
POD	The average serum concentration was estimated in the mice (8.29 mg/L) using a three-compartment pharmacokinetic model (Wambaugh et al. 2013) using animal species, strain, sex-specific parameters. (ATSDR 2018)
HED = POD × DAF (mg/kg/d)	DAF = Ke × Vd Ke = 0.000825175 (8.2 × 10-4) based on a human serum half-life of 840 days (Bartell et al. 2010) Vd = 0.17 L/kg (Thompson et al. 2010) $HED_{LOAEL} = POD_{LOAEL} \times DAF$ $HED_{LOAEL} = POD_{LOAEL} \times Ke \times Vd$ $HED_{LOAEL} = 8.29$ mg/L × 0.0000825175 × 0.17 L/kg $HED_{LOAEL} = 0.001163$ mg/kg/d or 1.163×10^{-3} mg/kg/d
Uncertainty Extrapolation	
Human Variability (UFH)	10 (standard)
Animal to Human (UFA)	3 (DAF applied)
Subchronic to Chronic (UFS)	1 (Chronic effect studied)
LOAEL to NOAEL (UFL)	10 (standard)
Database (UFD)	1
Total Composite (UFT)	300
RfD = HED/UFT (mg/kg/d)	RfD = 0.001163 mg/kg/d/300 RfD = 3.9 ng/kg/day (3.9×10^{-6} mg/kg/d)
THSV = POD / UFT	THSV= 8.29 mg/L/ 300 THSV= 0.028 mg/L
Receptor	Infant exposure via breastmilk for 1 year, from mother chronically exposed via water, followed by lifetime of exposure via drinking water. Protective for short-term, subchronic and chronic. (also protective of formula fed infant). Goeden Model Parameters: Placental transfer of 87% and breastmilk transfer of 5.2% (MDH (2020 PFOA)). The Human Serum half-life is set at 840 days (Bartell et al. 2010). The Volume of distribution of 0.17 L/kg (Thompson et al. [2010]) Other factors include, 95th percentile drinking water intake, consumers only, from birth to more than 21 years old. Upper percentile (mean plus two standard deviations) breast milk intake rate. Time-weighted average water ingestion rate from birth to 30-35 years of age is used to calculate maternal serum concentration at delivery. (Goeden et al. [2019]) A Relative Source Contribution of 50% (0.5) is applied and based on studies which showed that infants RSC is similar to NHANES 95th percentiles for 3—11 (2013-2014) and over 12 years old (2015-2016) participants. (CDC 2019)
Chronic Non-Cancer MCLG	The model produces a Chronic Non-Cancer MCLG of 8 ng/L (ppt). This protects health during the growth and development of a breast fed infant.

In summary, the DPAG recommended a chronic non-cancer MCLG for PFOA of 8 ng/L to protect breast-fed infants and throughout life.

The Board is setting the MCLG for PFOA at the DPAG recommended level of 8 ng/L.

PFOA—occurrence data

Table 4 is a summary of occurrence data for PFOA. The data includes 412 results from the PFAS Sampling Plan and detect data from 23 sites under UCMR 3 for a total of 435 sample results.

Table 4. PFOA Occurrence Data > MCLG of 8 ng/L

PFOA Occurrence Data > MCLG of 8 ng/L	
# of sites (of 435) > MCLG	46
% of sites > MCLG	10.6%
Estimated # of EPs (of 3,785) > MCLG	400

A review of occurrence data indicates that 46 EPs out of a total number of 435 EPs sampled exceeded the MCLG for PFOA of 8 ng/L. This represents 10.6% of all EPs

sampled. This exceedance rate may overestimate the exceedance rate for other PWSs in this Commonwealth that were not sampled because the occurrence data sampling predominately targeted sites near potential sources of PFAS contamination. However, the occurrence data provides the most relevant information currently available on the prevalence and levels of PFAS in PWSs in this Commonwealth. Applying the occurrence data PFOA MCLG exceedance rate (10.6%) to the total number of EPs for all applicable PWSs (3,785 EPs), it is estimated that 400 EPs will exceed the MCLG of 8 ng/L.

PFOA—MCL of 14 ng/L

The Board is setting an MCL of 14 ng/L for PFOA. The MCL is based on the health effects and MCLG, occurrence data, technical feasibility and costs and benefits.

Table 5 is a summary of occurrence data for PFOA when compared to the MCL of 14 ng/L.

Table 5. PFOA Occurrence Data > MCL of 14 ng/L

PFOA Occurrence Data > MCL of 14 ng/L	
# of sites (of 435) > MCL	25
% of sites > MCL	5.7%
Estimated # of EPs (of 3,785) > MCL	218

A review of occurrence data indicates that 25 EPs out of a total number of 435 EPs sampled exceeded the MCL for PFOA of 14 ng/L. This represents 5.7% of all EPs sampled. This exceedance rate may overestimate the exceedance rate for other PWSs in this Commonwealth that were not sampled because the occurrence data sampling predominately targeted sites near potential sources of PFAS contamination. However, the occurrence data provides the most relevant information currently available on the prevalence and levels of PFAS in PWSs in this Commonwealth. Applying the occurrence data PFOA MCL exceedance rate (5.7%) to the total number of EPs for all applicable PWSs (3,785 EPs), it is estimated that 218 EPs will exceed the MCL of 14 ng/L.

PFOS—DPAG development of MCLG

After a literature search and a review of the available evidence and recommendations from various agencies, the DPAG developed an MCLG recommendation for PFOS of 14 ng/L or ppt based on non-cancer endpoints. The DPAG referenced inputs from the EPA, ATSDR, MDH and MDHHS.

The DPAG selected Dong, et al. (2011) as the critical study, which identified immunotoxicity effects (such as immune suppression) as critical. The DPAG determined that a POD of 2.36 mg/L is appropriate. The DPAG followed the approaches used by MDHHS, MDH and the EPA to select and determine the Human Equivalent Dose (HED), Uncertainty Factors (UF), Reference Dose (RfD), Relative Source Contribution (RSC) and recommended MCLG. Table 6 provides a summary of the DPAG's derivation of the MCLG for PFOS.

Table 6. DPAG Derivation of PFOS MCLG (DPAG, January 2021)

PFOS	
Drexel PFAS Advisory Group (DPAG) 2021	
Dose Response Modeling Method	NOAEL
POD	2.36 µg/mL (or 2.36 mg/L)
HED = POD × DAF (mg/kg/d)	Toxicokinetic Adjustment based on Chemical—Specific Clearance Rate (Li et al 2018, MDH 2020 PFOS) DAF = Vd (L/kg) × (Ln2/Half-life, days) DAF = 0.23 L/kg × (0.693/1241 days) = DAF = 0.00013 L/kg/d HED = POD × DAF (mg/kg/d) HED = 2.36 mg/L × 0.00013 L/kg/d HED = 0.000307 mg/kg/d
Uncertainty Extrapolation	
Human Variability (UFH)	10
Animal to Human (UFA)	3 (DAF applied)
Subchronic to Chronic (UFS)	1
LOAEL to NOAEL (UFL)	1
Database (UFD)	3
Total Composite (UFT)	100
RfD = HED/UFT (mg/kg/d)	RfD = HED/UFT (mg/kg/d) RfD = 0.000307 mg/kg-d/100 RfD = 3.1 ng/kg/d or 3.1×10^{-6} mg/kg-d
THSV = POD/UFT	ITSHV = 2.36 mg/L/100 ITSHV = 0.024 mg/mL
Receptor	Infant exposure via breastmilk for 1 year, from mother chronically exposed via water, followed by lifetime of exposure via drinking water. Protective for short-term, subchronic and chronic. The 95th percentile water intake rates (Table 3-1 and 3-3, USEPA 2019) or upper percentile breastmilk intake rates (Table 15-1, USEPA 2019) were used. Breast-fed infant, which is also protective of a formula-fed infant using Minnesota Department of Health Model based on Goeden (2019). Placental transfer of 40% (MDH 2020 PFOS). Breastmilk transfer of 1.7% (MDH 2020 PFOS). Human Serum half-life of 1241 days (Li et

PFOS	
Drexel PFAS Advisory Group (DPAG) 2021	
	al. 2018) Volume of distribution of 0.23 L/kg (USA EPA 2016c) 95th percentile drinking water intake, consumers only, from birth to more than 21 years old (Goeden [2019]) Upper percentile (mean plus two standard deviations) breast milk intake rate (Goeden [2019]) Time-weighted average water ingestion rate from birth to 30—35 years of age (to calculate maternal serum concentration at delivery) (Goeden [2019])
Chronic Non-Cancer MCLG	The model produces a Chronic Non-Cancer MCLG of 14 ng/L (ppt). This protects health during the growth and development of a breast fed infant.

In summary, the DPAG recommended a chronic non-cancer MCLG for PFOS of 14 ng/L to protect breast-fed infants and throughout life.

The Board is setting the MCLG for PFOS at the DPAG recommended level of 14 ng/L.

PFOS—occurrence data

Table 7 is a summary of occurrence data for PFOS. The data includes 412 results from the PFAS Sampling Plan and detect data from 23 sites under UCMR 3 for a total of 435 sample results.

Table 7. PFOS Occurrence Data > MCLG of 14 ng/L

PFOS Occurrence Data > MCLG of 14 ng/L	
# of sites (of 435) > MCLG	23
% of sites > MCLG	5.3%
Estimated # of EPs (of 3,785) > MCLG	200

A review of occurrence data indicates that 23 EPs out of a total number of 435 EPs sampled exceeded the MCLG for PFOS of 14 ng/L. This represents 5.3% of all EPs sampled. This exceedance rate may overestimate the exceedance rate for other PWSs in this Commonwealth that were not sampled because the occurrence data sampling predominately targeted sites near potential sources of PFAS contamination. However, the occurrence data provides the most relevant information currently available on the prevalence and levels of PFAS in PWSs in this Commonwealth. Applying the occurrence data PFOS MCLG exceedance rate (5.3%) to the total number of EPs for all applicable PWSs (3,785 EPs), it is estimated that 200 EPs will exceed the MCLG of 14 ng/L.

PFOS—MCL of 18 ng/L

The Board is setting an MCL of 18 ng/L for PFOS. The MCL is based on the health effects and MCLG, occurrence data, technical feasibility and costs and benefits.

Table 8 is a summary of occurrence data for PFOS when compared to the MCL of 18 ng/L.

Table 8. PFOS Occurrence Data > MCL of 18 ng/L

PFOS Occurrence Data > MCL of 18 ng/L	
# of sites (of 435) > MCL	22
% of sites > MCL	5.1%
Estimated # of EPs (of 3,785) > MCL	191

A review of occurrence data indicates that 22 EPs out of a total number of 435 EPs sampled exceeded the MCL for PFOS of 18 ng/L. This represents 5.1% of all EPs sampled. This exceedance rate may overestimate the exceedance rate for other PWSs in this Commonwealth that were not sampled because the occurrence data sampling predominately targeted sites near potential sources of PFAS contamination. However, the occurrence data provides the most relevant information currently available on the prevalence and levels of PFAS in PWSs in this Commonwealth. Applying the occurrence data PFOS MCL exceedance rate (5.1%) to the total number of EPs for all applicable PWSs (3,785 EPs), it is estimated that 191 EPs will exceed the MCL of 18 ng/L.

State Data

Currently, seven other states have set regulatory limits for select PFAS, including PFOA and PFOS, as summarized in Table 9. The MCLs for the Commonwealth are of comparable magnitude as the other state standards.

Table 9. PFOA and PFOS MCLs from Seven Other States

	NY	*MI*	*NJ*	*NH*	*PA*	*MA*	*VT*	*WA*
PFOA	10	8	14	12	14	20*	20*	10
PFOS	10	16	13	15	18	20*	20*	15

*The MCL for MA & VT is for a group of five (VT) or six (MA) PFAS, including PFOA and PFOS (not individual contaminants).

Advisory Board review

The Public Water System Technical Assistance Center (TAC) Board—the primary advisory board for the Department's Safe Drinking Water Program—reviewed the draft proposed rulemaking on July 29, 2021, and unanimously supported the draft proposed rulemaking as it was presented. The TAC Board also expressed support for the draft proposed rulemaking in a letter dated July 30, 2021.

The TAC Board reviewed the draft final-form rulemaking on July 14, 2022, and unanimously supported the draft final-form rulemaking as it was presented. The TAC Board also expressed support for the draft final-form rulemaking in a letter dated July 18, 2022.

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E. *Summary of Final-Form Rulemaking and Changes from Proposed to Final-Form Rulemaking*

§ 109.1. Definitions

A definition for the acronym "CASRN—Chemical Abstracts Service Registry Number" is added because the CASRN numbers are included for each of the individual PFAS compounds included in the regulation.

A definition for "GAC—Granular Activated Carbon" is added because GAC is one of the treatment technologies considered acceptable for PFAS removal.

A definition for "MCLG—Maximum Contaminant Level Goal" is added. The definition is from 40 CFR 141.2 (relating to definitions) with added text referencing MCLGs established under both the Federal and State acts.

The acronym "MDL" is added to the existing definition "Method Detection Limit" with the amended definition alphabetically reordered. The definition for "Method Detection Limit" is also amended to be consistent with the current definition in the Federal regulations at 40 CFR Part 136 Appendix B (relating to definition and procedure for the determination of the method detection limit—revision 2).

A definition for "MRL—Minimum Reporting Level" is added.

Definitions for the following acronyms are added: "PFAS," "PFOA" and "PFOS." Definitions for individual compounds include the CASRN number to eliminate confusion as to the specific chemical form that is included in the regulation.

A definition for "Performance evaluation sample" is added to be consistent with Federal language.

The existing definition for "Reliably and consistently below the MCL" is amended to add "PFAS" defined as less than 80% of the MCL.

There is no change made to this section from the proposed rulemaking to this final-form rulemaking.

§ 109.202. State MCLs, MRDLs and treatment technique requirements

Subsection (a)(4) for "Other MCLs" adds MCLs and MCLGs for PFOA and PFOS, with an effective date of the

publication of this final-form rulemaking. The MCLs and MCLGs are listed in both milligrams per liter (mg/L), which are the traditional units for MCLs, as well as in nanograms per liter (ng/L) for clarity, because the numbers are so low.

There is no change made to this section from the proposed rulemaking to this final-form rulemaking.

§ 109.301. General monitoring requirements

The duplicated text in paragraph (2)(iv) through (iii) regarding performance monitoring for unfiltered surface water and groundwater under the direct influence of surface water (GUDI), which was inadvertently added following the last regulatory update at 48 Pa.B. 4974 (August 18, 2018), is deleted.

Paragraph (6)(vii)(A)(I) and (II) are amended for consistency with existing definitions that were amended in 2018 and to clarify that the Zone I and Zone II wellhead protection areas and the Zone A and Zone B surface water intake protection areas are defined in § 109.1 (relating to definitions). The amendments will apply to waivers issued for synthetic organic chemicals (SOCs).

Paragraph (8)(iii) is amended to clarify that consecutive water systems may be exempt from PFAS monitoring, in addition to volatile synthetic organic chemicals (VOCs), SOCs, inorganic chemicals (IOCs) and radionuclides.

Paragraph (9) is amended to clarify monitoring requirements for point-of-entry (POE) devices. A POE device is installed on the service line to a house, building or other facility for the purpose of reducing contaminants in the water distributed to that property and is used as an alternative to centralized water treatment. POE devices must meet design and construction standards and may only be used as a treatment option by very small PWSs that serve 100 or fewer people for treating sources that were permitted prior to 1992; the POE device must be installed on every connection unless the PWS can demonstrate that water provided to a service connection meets water quality standards. See § 109.612 (relating to POE devices). As a result, POE devices are often not cost effective and currently there are no PWSs in this Commonwealth that have a permit for POE devices. However, the Commonwealth is required to maintain requirements for POE devices to comply with Federal safe drinking water requirements. Consequently, monitoring requirements for POE devices are added for PFAS, as well as additional contaminants, as applicable, to correct the omission of paragraphs (10)—(15) and Subchapter K (relating to lead and copper). These requirements should have been added in previous rulemakings but were mistakenly overlooked due to no PWSs in this Commonwealth having a permit for POE devices.

Paragraph (11) is amended to clarify that for EPs that do not provide water continuously, monitoring for PFAS is not required during quarters when water is not provided to the public.

Paragraph (15)(i) and (ii) are amended to clarify monitoring for PFAS for reserve EPs and EPs that receive water from a reserve source.

There are no changes are made to paragraphs (2)—(15) from the proposed rulemaking to this final-form rulemaking.

Paragraph (16) describes new monitoring requirements for PFAS for community water systems and nontransient noncommunity water systems. Throughout paragraph (16), the provisions utilize terms of art and phrasing that mirror Federal safe drinking water regulations and are consistent with language used throughout the Department's safe drinking water regulations in Chapter 109.

Paragraph (16)(i)(A) and (B) specify the initial monitoring requirements for PFAS and, for this final-form rulemaking, are amended to improve readability by removing the phrase "for the PFAS listed in § 109.202(a)(4)(ii)(A) and (B)" because this cross reference is already stated in paragraph 16.

For this final-form rulemaking, proposed paragraph (16)(i)(C) is renumbered as (16)(i)(D) and new paragraph (16)(i)(C) is added in response to public comments to allow PWSs to request to modify the initial monitoring period required under paragraph (A) or (B) to coincide with monitoring required under the Fifth Unregulated Contaminant Monitoring Rule (UCMR 5). Water systems may adjust their UCMR 5 schedule to coincide with their initial monitoring begin date or submit a request to the Department to adjust their initial monitoring begin date to coincide with their UCMR 5 schedule.

Paragraph (16)(i)(D) specifies initial monitoring for new EPs permitted after the dates specified in clauses (A) and (B).

Paragraph (16)(ii) specifies the repeat monitoring frequency for PFAS that are detected during initial monitoring and, for this final-form rulemaking, is amended to improve readability and to remove the cross-reference to § 109.202(a) (relating to State MCLs, MRDLs and treatment technique requirements) because that cross reference is already stated in paragraph (16).

Paragraph (16)(ii)(A)—(C) are amended in this final-form rulemaking to be consistent with the definition for "reliably and consistently below the MCL" in response to public comments, to improve readability, to remove the cross-reference to § 109.202(a) because that cross reference is already stated in paragraph (16), and to clarify that repeat monitoring is for the detected PFAS, not for both PFOA and PFOS, signifying that monitoring requirements for PFOA and PFOS are independently determined, consistent with existing requirements for SOCs.

Paragraph (16)(iii) specifies the repeat monitoring frequency for PFAS that are not detected during initial monitoring and, for this final-form rulemaking, is amended to improve readability, to remove the cross-reference to § 109.202(a) because that cross reference is already stated in paragraph (16), and to clarify that reduced repeat monitoring applies to the PFAS that is not detected.

Paragraph (16)(iv) specifies the repeat monitoring frequency for PFAS that are detected above the MCL value and, for this final-form rulemaking, is amended to be consistent with the definition for reliably and consistently below the MCL in response to public comments, to improve readability, to remove the cross-reference to § 109.202(a) because that cross reference is already stated in paragraph (16), and to clarify that repeat quarterly monitoring is required for the PFAS exceeding its respective MCL.

Paragraph (16)(v) requires collection of confirmation samples for each PFAS detected in exceedance of its MCL and the timing for collection of confirmation samples.

Paragraph (16)(vi) specifies the repeat and performance monitoring requirements for EPs with PFAS removal treatment and, for this final-form rulemaking, is amended in response to public comments to clarify that performance monitoring may be required more frequently than quarterly, to improve readability, to remove the cross-reference to § 109.202(a) because that cross reference is

already stated in paragraph (16), and to clarify that where treatment is installed for removal of a PFAS, performance monitoring (and annual compliance monitoring) is required for the PFAS for which treatment has been installed.

Paragraph (16)(vii) describes the process by which systems may be able to obtain a monitoring waiver for PFAS and, for this final-form rulemaking, is amended to improve readability, to remove the cross-references to § 109.202(a) because that cross reference is already stated in paragraph (16), and to clarify that the waiver application is specifically for the PFAS monitored under paragraph (16)(ii) or the previously detected PFAS.

Paragraph (16)(viii) specifies when PFAS samples may be invalidated and utilizes the term "obvious sampling errors" consistent with 40 CFR 141.24(f)(13) and (h)(9) (relating to organic chemicals, sampling and analytical requirements).

Paragraph (16)(ix) specifies how compliance with the PFAS MCLs is determined.

§ 109.303. Sampling requirements

Subsection (a)(4) is amended to delete an incorrect cross reference to § 109.302(f) (relating to special monitoring requirements). The special monitoring requirements under § 109.302(f) relate to groundwater under the direct influence of surface water and are taken from the collection facilities (raw source water) and not the EP to the distribution system.

Subsection (a)(6)(i) specifies where samples are to be collected. For this final-form rulemaking, it is deleted and the language is moved to subsection (a)(6) because subsection (a)(6)(ii) is deleted.

Subsection (a)(6)(ii) is deleted in this final-form rulemaking in response to public comments requesting clarification on proper training for persons collecting PFAS samples. The Department did not intend to require extensive training or certification for sample collectors; the training conducted by accredited laboratory staff was intended to educate sample collectors on the preparation needed to minimize cross contamination of samples. The Department has determined that this information can be made available to sample collectors through guidance, so this requirement is deleted.

§ 109.304. Analytical requirements

Subsection (f) specifies the analytical requirements for the PFAS with an MCL.

Subsection (f)(1) specifies acceptable analytical methods and MRLs. The MRLs for PFOA and PFOS are set at 5 ng/L. This level was determined through the survey conducted by the Department of laboratories accredited by this Commonwealth for PFAS analysis. It was determined using the Department's experience with laboratories finding a balance between reporting to a low level and still meeting all method required quality control.

Subsection (f)(2) specifies the requirement that analysis must be conducted by a laboratory accredited by the Department.

Subsection (f)(3) specifies the requirement for laboratories to determine MDLs for each analyte.

Subsection (f)(4) specifies the requirements for laboratories to analyze performance evaluation samples at least annually.

Subsection (f)(5) requires that the MRL must be contained within the range of calibration.

There is no change made to this section from the proposed rulemaking to this final-form rulemaking.

§ 109.411. Content of a public notice

Subsection (e)(1) is amended for formatting purposes to place the existing requirement to use the health effects language for fluoride in each Tier 2 public notice into a separate subparagraph.

Subsection (e)(1)(i) includes the relocated requirement to use the health effects language for fluoride, which was previously included in § 109.411(e)(1) (relating to content of a public notice).

Subsection (e)(1)(ii) and (iii) adds the requirement to include the health effects language for PFOA or PFOS in each Tier 2 public notice for violation of the respective primary MCL, and includes the health effects language that must be used.

There is no change made to this section from the proposed rulemaking to this final-form rulemaking.

§ 109.416. CCR requirements

Paragraph (3) is amended to update the cross-reference to § 109.411(e)(1)(i), which contains the specific health effects language for fluoride required in a Tier 2 public notice.

Paragraph (3.1) adds consumer confidence report (CCR) reporting requirements for PFAS with an MCL.

Paragraph (3.1)(i)(A)—(G) specifies the information on detected results that must be reported.

Paragraph (3.1)(ii) requires that the respective health effects language in § 109.411(e)(1)(ii) and (iii) must be included for violation of a primary MCL for PFOA or PFOS.

There is no change made to this section from the proposed rulemaking to this final-form rulemaking.

§ 109.503. Public water systems construction permits

Subsection (a)(1)(iii)(D)(XIV.1) adds new source sampling requirements for PFAS.

There is no change made to this section from the proposed rulemaking to this final-form rulemaking.

§ 109.602. Acceptable design

Subsection (j) identifies treatment technologies considered acceptable by the Department for compliance with the PFAS MCLs.

There is no change made to this section from the proposed rulemaking to this final-form rulemaking.

§ 109.701. Reporting and recordkeeping

Subsection (a)(3)(ii) is amended to clarify that 1-hour reporting is required when a sample result requires collection of a confirmation or check sample. The word "confirmation" is added because the terms "check" and "confirmation sample" are often used interchangeably but each are used in different locations in § 109.301 (relating to general monitoring requirements). Under § 109.301(16)(v), a confirmation sample shall be collected when PFAS is detected in exceedance of its respective MCL.

There is no change made to this section from the proposed rulemaking to this final-form rulemaking.

§ 109.1003. Monitoring requirements

The provisions for this section utilize terms of art and phrasing that mirror Federal safe drinking water regulations and are consistent with language used throughout the Department's safe drinking water regulations in Chapter 109.

Subsection (a)(1)(xv) identifies the PFAS monitoring requirements for bottled, vended, retail and bulk (BVRB) water systems. Compliance monitoring for all BVRB systems begins January 1, 2024.

Subsection (a)(1)(xv)(A) identifies the PFAS monitoring exemption for BVRB systems that obtain finished water from another permitted public water system.

Subsection (a)(1)(xv)(B) identifies the initial PFAS monitoring requirements for BVRB systems. Initial monitoring consists of 4 consecutive quarters at each EP.

Subsection (a)(1)(xv)(C)(I) and (II) identify the repeat PFAS monitoring requirements for BVRB system and, in this final-form rulemaking, are amended to be consistent with the definition for "reliably and consistently below the MCL" in response to public comments, to improve readability, to remove the cross-reference to § 109.202(a) because that cross reference is already stated in paragraph (1)(xv), and to clarify that the repeat monitoring frequency is determined independently for each individual PFAS.

Subsection (a)(1)(xv)(D) identifies the confirmation sampling requirements for PFAS monitoring for BVRB systems that detect a PFAS in exceedance of its MCL during annual monitoring.

Subsection (a)(1)(xv)(E) identifies the repeat and performance PFAS monitoring requirements for BVRB systems with PFAS removal treatment. In this final-form rulemaking, this clause is amended in response to public comments to clarify that performance monitoring may be required more frequently than quarterly in a permit special condition.

Subsection (a)(1)(xv)(F)(I) and (II) specify when PFAS samples may be invalidated for BVRB systems and utilize the term "obvious sampling errors" consistent with 40 CFR 141.24(f)(13) and (h)(9).

Subsection (a)(1)(xv)(G) identifies how compliance with the PFAS MCLs is determined for BVRB systems.

Subsection (b)(3) is amended to clarify that sampling and analysis for PFAS must be in accordance with the requirements in § 109.304 (relating to analytical requirements).

There is no change made to subsection (b)(3) from the proposed rulemaking to this final-form rulemaking.

Subsection (b)(6) was proposed to be amended to delete language that is also in subsection (b)(3) and to add the requirement that compliance monitoring samples for PFAS for BVRB systems must be collected by a properly trained sample collector. However, in this final-form rulemaking this requirement is deleted in response to public comments requesting clarification on proper training for persons collecting PFAS samples. The Department did not intend to require extensive training or certification for sample collectors; the training conducted by accredited laboratory staff was intended to educate sample collectors on the preparation needed to minimize cross contamination of samples. The Department has determined that this information can be made available to sample collectors through guidance, so this requirement has been deleted and subsection (b)(6) is reserved.

§ 109.1403. Monitoring waiver fees

Subsection (a) is amended to add a PFAS use waiver fee of $100.

There is no change made to this section from the proposed rulemaking to this final-form rulemaking.

F. *Summary of Comments and Responses on the Proposed Rulemaking*

The Board adopted the proposed rulemaking at its November 16, 2021, meeting. The proposed rulemaking was published at 52 Pa.B. 1245 (February 26, 2022). Five virtual public hearings were held the week of March 21—25, 2022. The 60-day public comment period on the proposed rulemaking closed April 27, 2022. The Board received more than 3,500 comments on the proposed rulemaking, including comments from members of the General Assembly, the House Environmental Resources and Energy Committee, the Independent Regulatory Review Commission (IRRC), public advocacy groups, and a variety of industries.

The comments received on the proposed rulemaking are summarized as follows and are addressed in more detail in a comment and response document that accompanies this final-form rulemaking.

Regulating PFAS as a class

IRRC and several commentators commented regarding the reasonableness of regulating PFOA and PFOS as individual compounds rather than as a class. Through a toxicology services contract with the Department, the DPAG determined that currently available scientific evidence does not appear to support a decision to use a cumulative or summative approach for regulating PFAS because using a combined approach for a drinking water standard for PFAS appears to be a "shortcut based on a presumption that the agents all have similar health effects and endpoints" (DPAG, 2021). The DPAG determined that it could not be assumed that all PFAS have shared hazard traits and target the same health endpoints, and that the best approach, which is most protective of public health, was to develop individual MCLGs for each PFAS requested by the Department, and the DPAG recommended that each PFAS compound be reviewed and MCLs determined individually. Additionally, the occurrence data used by the Department in development of this final-form rulemaking did not suggest a meaningful opportunity to regulate other PFAS compounds besides PFOA and PFOS. Based on the determination and recommendation from the DPAG, the Department moved forward with evaluating each PFAS individually to determine which ones to regulate and at what levels.

Forthcoming Federal regulations

IRRC, the House Environmental Resources and Energy Committee and several commentators expressed concerns regarding the promulgation of potentially overlapping and differing Federal and State regulations related to PFOA and PFOS in drinking water. The EPA has publicly stated its intent to publish a proposed PFAS National Primary Drinking Water Regulation in December 2022, and a final regulation in December 2023. While there are no guarantees that the Federal government will publish a proposed rule as stated in December 2022, when the EPA's proposed rule is published, the Department will review the proposal and provide comments during the public comment period. As a basis for providing comments on a proposed Federal rule, the Department will rely on the rigorous rulemaking process by which this final-form rulemaking was developed, a process which identified where PFAS was present and provides justification for the Board's MCLs. Sometime after the closing of the comment period on the EPA's proposed rulemaking, the EPA will publish a final rule.

Since a proposed Federal rule has not yet been published, it is impossible to predict whether the EPA will

adhere to its intended schedule and publish a final rule in December 2023. However, when a final Federal rule is published, the regulations will go into effect 3 years after they are finalized. During this 3-year period, the Department will review the Federal rule and evaluate the supporting documentation to determine how the Federal rule compares to the Department's regulations. If the Federal rule is more stringent, the Department will follow the Commonwealth's rulemaking process to revise its regulation to address any discrepancies and to ensure the Department's regulations meet at least the minimum Federal requirements. If the final Federal rule is less stringent than the Department's regulations, the Department will evaluate the Federal rule and its supporting documentation to determine if any revisions are needed to the Department's regulations.

Setting MCLs ahead of EPA is expected to provide more timely protection of public health while imposing minimal additional regulatory requirements on the regulated community. Under this final-form rulemaking, PWSs will be required to conduct monitoring for PFOA and PFOS earlier than may be required under Federal regulations, and if levels are in violation of one or both MCLs, PWSs will be required to complete corrective actions sooner. If the EPA ultimately sets MCLs that are less stringent, there may be some PWSs required to install treatment under this rule that would not have been required to under the EPA's levels; however, through the rulemaking process, the Department has demonstrated that the MCLs in this final-form rulemaking are in the interest of improved public health protection and reasonably balance costs and benefits. If the EPA's MCLs are more stringent, there will likely be additional PWSs that will need to install treatment beyond those that exceed the MCLs in this final-form rulemaking. For the PWSs that install treatment as a result of a violation of the MCLs in this final-form rulemaking, that treatment will put those PWSs in a better position to comply with the EPA's MCLs regardless of whether they are more or less stringent. The approved treatment technologies in this final-form rulemaking are capable of treating PFOA, PFOS and other PFAS to non-detectable levels. If the EPA's MCLs are more stringent, those PWSs that have installed treatment as required by this final-form rulemaking may need to make relatively minor operational adjustments, such as changing out the media more frequently, but large-scale design changes are not expected.

It is the Board's position that in the interest of improved public health protection, it is imperative to move forward with this final-form rulemaking at this time and not delay implementation. The Department has a responsibility to protect this Commonwealth's drinking water. Recent research suggests that the EPA's 2016 Combined Lifetime HAL for PFOA and PFOS of 70 ng/L is not sufficiently protective against adverse health effects. Although the EPA has started the process of setting more stringent standards for PFOA and PFOS in drinking water, that process is expected to take years to complete. Even if the EPA meets its stated goal of publishing a final rulemaking by the end of 2023, there will be delayed implementation of the Federal rule to allow states to incorporate the final regulation. Therefore, the Federal standards would not be in place until late 2026 at the earliest. For that reason, it is important that the Board act now to set more protective standards for this Commonwealth, to protect the health of residents in this Commonwealth.

Use of UCMR 5 data for compliance

IRRC and several commentators recommended that the regulation allow UCMR 5 monitoring data to be used for compliance with the initial monitoring period of the proposed rulemaking. The Board agrees and has amended this final-form rulemaking to include a clause in the initial monitoring requirements in § 109.301(16)(i) that allows for a modification of the timing of the initial monitoring period to coincide with UCMR 5 monitoring. This may allow some systems to realize cost savings by preventing duplicate analyses if they meet all requirements. To modify the initial monitoring period, a PWS must request this change and the Department must approve it in writing. The Department will provide details on how to modify the initial monitoring schedule in guidance.

It is the responsibility of the PWS to ensure, if so desired by the PWS, that the schedules for initial compliance monitoring for this final-form rulemaking and for UCMR 5 monitoring coincide, and to request a schedule change, if necessary, for either UCMR 5 monitoring or for initial compliance monitoring for this final-form rulemaking. Details about how PWS can request schedule changes for UCMR 5 monitoring are provided in the comment and response document that accompanies this final-form rulemaking.

For the same set of data to count toward both UCMR 5 monitoring and initial compliance monitoring for this final-form rulemaking, the data must meet requirements of both rules. For initial compliance monitoring for this final-form rulemaking, monitoring must be conducted according to all requirements in this final-form rulemaking, such as analyses being conducted by a Commonwealth-accredited laboratory using an approved method, and data being reported appropriately and on time, and other requirements in this final-form rulemaking. For UCMR 5 monitoring, analyses must be conducted by an EPA-approved laboratory for UCMR 5 using the UCMR 5-specified method and the monitoring must meet all requirements of the published UCMR 5. Therefore, if a PWS wishes to have the same data reported for both UCMR 5 monitoring and for initial compliance monitoring for this final-form rulemaking, it is the responsibility of the PWS to ensure that the monitoring schedules align, and that the lab conducting the analysis is both Commonwealth-accredited and UCMR 5-approved, using an appropriate method, and is amenable to reporting the same data twice, including meeting Commonwealth and UCMR 5 reporting requirements.

Laboratory capacity

IRRC and several commentators raised concerns regarding laboratory capacity, and requested the Board provide information on the number and capacity of laboratories certified to perform required testing for implementation of this final-form rulemaking. The Department conducted a survey of laboratories accredited by the Commonwealth for analysis of PFAS by one or more of the three approved methods in this final-form rulemaking. The purpose of the survey was to collect data on laboratory capacity, services provided, analytical costs and minimum reporting levels to assess the technical feasibility and analytical cost estimates of the proposed rulemaking. The results indicate more than sufficient capacity for compliance monitoring requirements of this final-form rulemaking. Details about the survey responses are provided in the comment and response document that accompanies this final-form rulemaking.

Cost estimates and sources of funding

IRRC and several commentators submitted comments regarding cost estimates and funding sources.

There are currently several funding sources available to PWSs for PFAS treatment costs. The Pennsylvania Infrastructure Investment Authority's Per- and Polyfluoroalkyl Substances Remediation Program is currently available to remediate PFAS contamination or presence in the water supply of public drinking water supply systems not related to the presence of a qualified former military installation. The Federal Infrastructure Investment and Jobs Act (IIJA) also provides relevant funding, including $4 billion Nationally in Drinking Water State Revolving Fund (DWSRF) moneys for projects to address emerging drinking water contaminants like PFAS and $5 billion Nationally in grants to small and disadvantaged communities for projects addressing emerging drinking water contaminants like PFAS. Over 5 years, the Commonwealth's allocation of these IIJA funds is expected to be $116 million in DWSRF emerging contaminants funds and an additional $140.5 million in funding for projects addressing emerging drinking water contaminants in small and disadvantaged communities, for a total of $256.5 million.

Cost estimates are based on a survey of costs from vendors and systems that have installed PFAS treatment. The sizes of the treatment systems of respondents varied from 0.005 million gallons per day (MGD) to 2.88 MGD and costs for these systems ranged from approximately $47,000 to $3,250,000, respectively. The survey showed generally lower capital and operational costs for smaller systems and increased costs as the volume of water treated increases; however, capital costs can vary greatly based on site-specific needs. Some systems may need infrastructure upgrades above and beyond the cost of the PFAS treatment, such as new well pumps, booster pumps and buildings to house the treatment, whereas other systems may only need to purchase and install the PFAS treatment equipment and media.

The Board requested comments on the proposed rulemaking regarding anticipated costs to comply with the proposed MCLs, including costs to design, install and operate treatment and other remedies. Although some comments were submitted expressing concerns about potentially high costs of treatment for PFAS removal, no comments were submitted with specific details regarding anticipated costs to comply with the MCLs.

Byproducts of treatment technologies

IRRC and several commentators submitted comments suggesting the Board should address implementation concerns related to byproducts of treatment technologies for PFAS removal. The Department requires a person to obtain a permit prior to constructing or modifying a PWS. As per this permitting process, the water system must demonstrate it will properly dispose of any untreated PFAS contaminated waters and spent media. Industrial discharges, such as wastewater from drinking water treatment that contain PFAS wastes, would not be acceptable to discharge to an on-lot or municipal wastewater system. Spent media will need to be disposed to an appropriate landfill or an incinerator.

Regarding the costs associated with disposing of byproducts of treatment technologies (such as spent treatment media), the Department conducted a survey of PWSs currently treating for PFAS, other state agencies and water treatment manufacturers to evaluate treatment technologies and treatment costs. Information regarding disposal costs were included in this survey. For example, it is the Board's understanding that GAC manufacturers are accepting used media from PWSs to either regenerate the media or incinerate or dispose of the media properly.

Cost-benefit analysis

IRRC and several commentators submitted comments indicating that the Board should address concerns regarding the cost/benefit analysis, including comments that the benefits were not quantified or estimated, clarification on the basis for 90% improvement compared with the EPA's 2016 Combined Lifetime HAL for PFOA and PFOS as a goal for benefits, and how increasingly stringent drinking water values affect health outcomes. The Department conducted several surveys to gather information to estimate monitoring and treatment costs of the rule. The information from the surveys was used along with the occurrence data to conduct the cost and benefit analysis. The Department estimated treatment costs at the MCLGs, the 2016 EPA HAL of 70 ppt, and several values in between, including the MCLs. Actual costs are likely to vary greatly based on site-specific needs. The selection of a 90% reduction in adverse health effects as a goal for improved public health protection was selected to be consistent with other existing drinking water standards, including the requirement to achieve at least a 90% inactivation of *Giardia* cysts using disinfection processes within a filtration plant.

To provide additional information to support the cost to benefits analysis, the Department extended the contract with Drexel University and charged the DPAG with estimating monetized benefits expected to be realized from implementation of the MCLs. Details about the DPAG's analysis of benefits/cost savings can be found in section G of this preamble. In summary, the DPAG determined the PFOA MCL of 14 ng/L is estimated to result in health care cost savings of $583 million over an 11-year period, or $53 million per year. Additionally, using a value transfer methodology, the DPAG estimated an annual monetized impact of elevated mortality due to PFAS exposure of $2 billion to $3.3 billion for the 11.9 million residents of this Commonwealth served by public water. This suggests that PFAS contamination in drinking water may account for 2% to 3% of the annual health care costs in this Commonwealth, which are estimated by the Kaiser Family Foundation (KFF 2022) at $120 billion annually. The DPAG also used a blood serum PFAS calculator to: (1) confirm that the MCL of 14 ppt for PFOA would provide a 90% improvement in blood serum levels compared to the serum level predicted at the 2016 EPA HAL of 70 ppt; and (2) demonstrate that increasingly stringent drinking water values (that is, lower concentrations of PFAS in drinking water) are expected to result in improved health outcomes.

Additional information on costs and benefits are detailed in section G of this preamble, as well as the comment and response document that accompanies this final-form rulemaking.

Scientific foundation and implications of future advances in scientific understanding about PFAS

IRRC and several commentators urged the Board to address concerns related to acceptable data and explain how the data supporting this final-form rulemaking protects public health. These commentators also recommended the Board explain how the standards in this final-form rulemaking may be revised in the future based on improved scientific understanding about exposure, dose and toxicology.

In determining recommended MCLGs, the DPAG used an evidence-based approach to independently review the available studies and to select critical health effects and critical studies for the PFAS evaluated. The scientific studies reviewed by the DPAG, including their strengths and weaknesses, are discussed fully and cited in the PFAS Workbook and MCLG Report. References reviewed by the Department, including the DPAG deliverables, are cited in this final-form rulemaking. The DPAG provided substantial justification in the MCLG Report for the selection of critical health effects and critical studies, based on the extensive expertise of the group. The Department used the MCLG recommendations from the DPAG's MCLG Report as the basis for development of MCLs.

In addition to the toxicology services contract, the Department's Safe Drinking Water Program developed and implemented the PFAS Sampling Plan to prioritize PWS sites for PFAS sampling and generate Statewide occurrence data. That occurrence data was extrapolated across all applicable PWSs and EPs and was ultimately used to inform the decision on which PFAS to regulate and to estimate the number of PWSs that may potentially have levels of PFAS exceeding various MCL levels.

As detailed in section G of this preamble, the Department also conducted several surveys to gather information to support development of this final-form rulemaking. The Department used the information gathered from these surveys to: consider available analytical methods, minimum reporting levels, laboratory capacity and analytical costs; evaluate treatment technologies and costs of installation and maintenance of treatment options; and, along with the occurrence data, to conduct the cost and benefit analysis.

This final-form rulemaking is designed to improve public health protections for residents of this Commonwealth based on scientific studies and data available at the time this final-form rulemaking was developed. Current research indicates that the EPA 2016 Combined Lifetime HAL of 70 ng/L for PFOA and PFOS is not sufficiently protective of public health. Implementing the MCLs in this final-form rulemaking will provide an increased measure of public health protection by resulting in lower levels of PFOA and PFOS in drinking water provided to PWS customers in this Commonwealth. Therefore, it is the Board's position that it is imperative to move forward at this time with this final-form rulemaking in the interest of improved public health protection. The Department will continue to review and evaluate emerging science and recommendations from experts in the field of toxicology, including recommendations from the EPA's Science Advisory Board, and the Department will consider future revisions to this rule as deemed necessary. If the Department determines that revisions to this rule are needed in the future, the Department will initiate and follow the Commonwealth's rulemaking process.

Lower MCLs

IRRC and numerous commentators submitted comments indicating that the proposed MCLs should be lower and requesting that the Board explain how it determined that the MCLs for PFOA and PFOS in this final-form rulemaking protect the health, safety and welfare of children, particularly young children. As detailed in section D of this preamble, the Department is required to follow a rigorous process when setting an MCL, a process which includes estimation of health risk reduction benefits.

As noted in section D of this preamble and in the MCLG Report, the DPAG was charged with developing recommended MCLGs at concentrations that were focused solely on protection of human health. The DPAG identified the target population for PFOA and PFOS as infant exposure by breastmilk for 1 year, from mother chronically exposed by means of water, followed by lifetime of exposure by means of drinking water. The DPAG noted in the MCLG Report that the recommended MCLGs for PFOA and PFOS are at levels intended to "protect breastfed infants and throughout life" (DPAG, 2021).

The MCLs of 14 ng/L for PFOA and 18 ng/L for PFOS are based on the health effects and MCLGs, occurrence data, technical feasibility and costs and benefits.

As detailed in section G of this preamble, in evaluating the costs and benefits, the Board compared costs for several possible values for the proposed MCLs, including the 2016 EPA HAL of 70 ppt, the MCLG, and several levels in between. The Board's goal was to provide at least a 90% reduction in adverse health effects (a 90% improvement in health protection) when compared to the 2016 EPA HAL of 70 ng/L. This goal is consistent with several existing drinking water standards. The Board believes that the MCLs for PFOA and PFOS strike an appropriate balance between the benefits (90% and 93% improvement in public health, respectively) and costs (253% and 94% increase in costs, respectively) when compared to the benefits and costs associated with meeting the 2016 EPA HAL. Additionally, the total estimated treatment and monitoring costs are offset by the total estimated health care cost savings of at least $53 million annually.

Effective dates

IRRC and numerous commentators requested that the Board explain how it determined that the effective dates in this final-form rulemaking balance protection of the public, health, safety and welfare with the economic impacts of implementation. According to this final-form rulemaking, initial compliance monitoring for systems serving a population of greater than 350 persons begins January 1, 2024, and initial monitoring for systems serving a population of less than or equal to 350 persons begins January 1, 2025. However, the MCLs will be effective upon publication of this final-form rulemaking, expected in early 2023. Water systems may begin to sample for PFAS voluntarily at any point. Additionally, water systems may be required to sample for contaminants identified in UCMR5 (including 29 PFAS compounds) as soon as January 2023.

The 2024 and 2025 initial compliance monitoring dates were selected to provide adequate time for water systems to plan for additional sampling that will be required at each EP and to incorporate the cost of additional sampling and analysis into their 2024 or 2025 budgets. Requiring all systems to begin monitoring immediately in 2023 would overwhelm sample capacity at accredited laboratories. The phased sampling approach focuses on analyzing the drinking water of as many consumers as possible earlier in implementation of this final-form rulemaking. In addition, a delay in initial monitoring until January 2024 will provide adequate time for water system personnel to learn the regulatory requirements and to train personnel. PFAS sample collection requires strict adherence to the method and trained samplers. The Department intends to conduct training in 2023 on implementation of this final-form rulemaking and on sample collection techniques.

Monitoring frequency

IRRC and several commentators submitted comments indicating that the Board should explain how the frequency of monitoring required in this final-form rulemaking is reasonable and protects public health, safety and welfare and whether a shorter monitoring timeframe following a detection was considered. In the existing 40 CFR Part 141 National Primary Drinking Water Regulations and Chapter 109 Safe Drinking Water regulations, there is a cohesive strategy for setting monitoring frequencies. For a specific contaminant, the monitoring frequency is set according to whether the contaminant is expected to cause potential adverse health effects from short-term acute exposure or long-term chronic exposure at concentrations likely to be detected in drinking water. Contaminants in the chronic group, including VOCs and SOCs, are monitored for compliance according to a schedule based on the EPA's Standardized Monitoring Framework (SMF), with monitoring occurring quarterly or less frequently, based on previous results and whether treatment is installed for a particular contaminant. The PFAS monitoring framework in this final-form rulemaking originated in existing monitoring requirements for the organic contaminants that already have MCLs, namely, the VOCs and SOCs. PFAS are a class of SOCs, and this final-form rulemaking adds two PFAS, PFOA and PFOS, to the chronic contaminant group. To be consistent with the EPA's SMF, this final-form rulemaking does not require monthly compliance monitoring of PFOA and PFOS.

Initial monitoring for VOCs, SOCs and PFAS is based on the EPA's SMF and consists of four consecutive quarterly samples. This will produce results that are representative of each calendar quarter, thereby representing any seasonal variations that could potentially occur. If PFOA or PFOS or both are detected at a level greater than their respective MCL during initial monitoring, compliance monitoring is required quarterly. When sample results indicate a violation of one or both MCLs, follow-up actions are required, including 1-hour notification to the Department, consultation with the Department on appropriate corrective actions, and Tier 2 public notification (PN). Once an MCL violation occurs and a PWS issues Tier 2 PN and begins taking corrective actions to comply with one or both MCLs, there is no significant health or information benefit obtained from conducting compliance monitoring for these chronic contaminants at the EP more frequently than quarterly.

Waivers

IRRC and numerous commentators requested the Board explain how it determined that the granting of waivers will not negate the protection of the public health, safety and welfare afforded by consistent testing. The PFAS waiver framework follows the existing waiver framework for VOCs, which is significantly more limited than the waiver framework for SOCs. Under this final-form rulemaking, a PWS can only apply for a waiver after the PWS completes 3 consecutive years of quarterly or annual samples with no detection of PFOA or PFOS. Waivers are only available at EPs supplied by groundwater or GUDI. Waivers are available after evaluating land use and the use of PFAS in wellhead protection area Zone II. The granting of waivers is at the Department's discretion.

The waiver process is a balance between requiring monitoring protective of public health and allowing a reduction in monitoring when a PFAS has an isolated appearance, has exited the system, decreases below the minimum reporting level and there is no known use of it near the groundwater source. Therefore, monitoring is only reduced when there is no expectation a PFAS detection will recur. There are a number of conditions that must be met for a waiver to be granted and the granting of waivers will not negate the protection of public health.

Achieving compliance

IRRC and several commentators requested the Board explain how it will ensure that compliance is achieved by water systems and that, following an MCL exceedance, a water system would not remain in the state of repeat monitoring and never reach compliance. Under existing authorities in § 109.701(a)(3)(i) (relating to reporting and recordkeeping), PWSs are required to notify the Department within 1 hour if any single sample result exceeds an MCL value or if the system is determined to be in violation of an MCL, according to § 109.301(16)(ix) for PFOA and PFOS. An initial consultation with the Department typically occurs during this notification regarding any immediate actions. When a PWS is in violation of an MCL, the Department issues a Notice of Violation (NOV) which contains requested actions and associated timeframes, including a request for the PWS to consult with the Department to determine appropriate corrective actions. In addition to issuing PN, corrective actions may include additional monitoring, installation of treatment, using alternative sources, blending sources or taking a source offline. PWSs are responsible for taking any and all corrective actions necessary to protect public health.

When systems fail to take corrective action and continue to be in violation of an MCL, the Department identifies the ongoing MCL violation as a significant deficiency which is defined in § 109.1. The Department notifies the PWS of the ongoing MCL violation and the identification of the ongoing violation as a significant deficiency through an NOV. This NOV outlines the regulatory responsibilities of systems as stipulated in § 109.717 (relating to significant deficiencies) for responding to significant deficiencies.

The exact corrective actions in response to an MCL violation are not codified in regulation because they are case specific and may vary based on each individual situation and system specific considerations, including the level detected, any known or suspected source of contamination, other water sources available and treatment processes already in place. Sufficient quarterly monitoring data may be necessary to evaluate whether there are seasonal variations in contaminant levels to identify the most appropriate corrective actions.

Invalidation of sample results

IRRC and a commentator recommended that the Board clarify implementation related to the invalidation of PFAS samples as provided in § 109.301(16)(viii)(A) of the proposed rulemaking. The language used in § 109.301(16)(viii) matches that already in use for the other groups of regulated organic chemicals, the VOCs and SOCs. As specified in § 109.304(f)(1), "Sampling and analysis shall be according to the following approved methods" which include EPA Method 533, EPA Method 537.1 or EPA Method 537 Version 1.1. Failure to follow the "Sample Collection, Preservation, and Storage" steps in the chosen method could result in sample invalidation. Decisions about sample invalidations will be based on available documentation. For example, if a sample is taken at a tap other than the EP, that error would have to be determinable from documentation. If PFOA or PFOS

is detected in a field reagent blank sample, it could be considered an obvious sampling error, if there is evidence that indicates PFOA or PFOS was introduced by the sampler. Obvious sampling errors will be further addressed in guidance materials and in training, which will be provided by the Department after this final-form rulemaking is promulgated.

Compliance determinations

IRRC and some commentators advised the Board to clarify how compliance determination will be implemented for systems that choose to monitor more frequently than required. Compliance will be determined according to § 109.301(16)(ix)(A) and (B). According to § 109.301(16)(ix)(A), "For systems monitoring more than once per year, compliance with the MCL is determined by a running annual average of all samples taken at each entry point." The running annual average (RAA), as defined in § 109.1, is the "average, computed quarterly, of quarterly arithmetic averages of all analytical results for samples taken during the most recent 4 calendar quarters." Therefore, individual monthly results will not be used directly for compliance; instead, the monthly results will be averaged within each calendar quarter to calculate a quarterly average, and then compliance is determined using that quarterly average. According to § 109.301(16)(ix)(B), "If monitoring is conducted annually or less frequently, the system is out of compliance if the level of a contaminant at any entry point is greater than the MCL. If a confirmation sample is collected as specified in subparagraph (v), compliance is determined using the average of the two sample results."

Compliance is determined based on the monitoring frequency in use and not on the monitoring frequency required. For example, if a system required to monitor annually is monitoring quarterly, compliance will be determined according to § 109.301(16)(ix)(A). As another example, if a system required to monitor quarterly is monitoring monthly, a quarterly average will be calculated with the monthly results each quarter and those quarterly averages will be used to calculate compliance according to § 109.301(16)(ix)(A).

IRRC and some commentators also advised the Board to clarify whether a determination of "out of compliance" will begin with the first sampling following the effective date of the regulation, and whether a system will be out of compliance if the first sample exceeds the MCL. During the initial year of quarterly compliance monitoring, compliance with each MCL will be determined by an RAA of all sample results for each of the regulated PFAS. During the first year of monitoring, results will not exist for all four of the most recent calendar quarters until the result from the fourth quarter is available. Until that point, results that do not yet exist are assumed to be less than the MRL and, thus, are entered as zero in the RAA calculation. If a system fails to collect a sample in all quarters of the initial year of compliance monitoring, then, in accordance with § 109.301(16)(ix)(D), compliance with the MCL will be based on the total number of quarters in which results were reported. According to § 109.301(16)(ix)(C), "If any sample result will cause the running annual average to exceed the MCL at any entry point, the system is out of compliance with the MCL immediately." For example, if the first quarterly result of initial compliance monitoring is more than four times the MCL, the system is out of compliance based on the compliance calculation for the first quarter of initial quarterly monitoring. However, if the first quarterly result is at a level that is over the MCL but not over four times the MCL, the system would not be out of compliance.

Analytical requirements

IRRC and a commentator advised the Board to explain the need for and reasonableness of retaining analytical requirements in this final-form rulemaking instead of including those requirements in guidance or codifying those requirements in the Department's Environmental Laboratory Accreditation regulations in Chapter 252 (relating to environmental laboratory accreditation). The existing analytical requirements have been established through § 109.304(a), which states "Sampling and analysis shall be performed in accordance with analytical techniques adopted by the EPA under the Federal Act or methods approved by the Department." The analytical techniques adopted by the EPA under the Federal Act are specified explicitly in the National Primary Drinking Water Regulations in 40 CFR Part 141 Subpart C (relating to monitoring and analytical requirements). However, the EPA has not yet adopted analytical techniques for PFAS in 40 CFR Part 141 Subpart C. Therefore, in accordance with § 109.304(a), the Department is responsible for approving methods for PFAS analysis. Updating Chapter 252 would require a procedure equivalent to updating Chapter 109, so there would be no flexibility gained from listing the methods in Chapter 252 instead. By explicitly specifying these methods in § 109.304(f), the Department is following the EPA's convention.

Treatment technology piloting

IRRC and a commentator advised the Board to clarify whether piloting will be required for the approved treatment technologies listed in the proposed rulemaking, and, if so, to amend this final-form rulemaking and associated documents to take the additional costs and economic impacts into consideration. The Department currently is not requiring PWS to pilot all PFAS treatment projects. However, the Department retains the right to require piloting even if the technology is listed as approved in regulation, as the Department can for all types of treatment processes. The Department encourages piloting for the technology listed as approved for PFAS treatment to develop site-specific design requirements. For systems that have provided successful demonstration of a technology on similar water quality, the Department has not required a pilot study. The PWS is responsible for demonstrating similarity in water quality to the Department.

Other treatment technologies

Commenting on proposed § 109.602(j)(2) (relating to acceptable design), IRRC asked the Board to explain what standards would determine if an alternate treatment technology has demonstrated the capability to provide an adequate and reliable quantity and quality of water to the public, and clarify how this provision will be implemented. This provision will be implemented in the same manner in which it would be for any other contaminant or any innovative treatment technology; it is addressed in Section I.C. of the Department's Public Water Supply Manual Part II, Community System Design Standards (383-2125-108).

Regulatory initiatives for PFAS source control requirements

IRRC and a commentator advised the Board to address the impact of other regulatory initiatives related to PFAS source control requirements on the economic impacts of this final-form rulemaking. Although these issues are outside the scope of this final-form rulemaking, the Board

notes that, as part of the multi-agency PFAS Action Team established by Governor Tom Wolf, the Department is actively exercising its statutory authorities to implement regulatory and permitting initiatives to address PFAS contamination.

In November 2021, the Board promulgated regulatory provisions in Chapter 250 (relating to administration of the land recycling program) to address PFAS contamination in soil and groundwater. The regulatory provisions established soil and groundwater Medium Specific Concentrations (MSC) for PFOS, PFOA and PFBS under the Statewide Health Standard. Through this update, remediators must demonstrate attainment of a standard provided by the Land Recycling and Environmental Remediation Standards Act (35 P.S. §§ 6026.101—6026.908) (Act 2) and obtain Act 2 liability relief for PFOA, PFOS and PFBS. By law, the Department is required to review these standards every 36 months to ensure the MSCs reflect the most current science available to protect human health and the environment. When a Federal or State MCL is published, it will become the updated MSC as required by Act 2.

The Department also recently established a multi-pronged strategy to better characterize and control PFAS in permitted discharges to surface waters by implementing monitoring and other requirements in National Pollutant Discharge Elimination System (NPDES) permits. The Department's PFAS strategy for NPDES discharges includes: identifying industries likely to discharge PFAS; revising NPDES permit applications for these industries and for major sewage facilities receiving discharges from these industries to include PFOA and PFOS sampling requirements and, where relevant, source evaluations; and adding monitoring requirements for PFOA and PFOS to NPDES permits from facilities with identified elevated concentrations in their effluent and, where necessary, evaluating the need for effluent limits for those facilities.

Private water wells

Most commentators noted that many residents of this Commonwealth receive their water from private water sources, including private wells, and requested that the Board include private water sources in the requirements of the proposed rulemaking.

However, the Board does not have the authority to regulate private water sources. Section 4 of the act states that rules and regulations established by the Board "shall apply to each public water system in the Commonwealth. . ." Section 3 of the act (35 P.S. § 721.3), defines a public water system as "a system for the provision to the public of water for human consumption which has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year."

The act grants authority for the Board to establish rules and regulations that govern only public water systems, not private water systems (which include privately owned water wells). The act additionally grants authority to the Department to enforce only Federal and State regulations regarding well design and construction standards and drinking water standards. As Federal standards and State standards established by the Board govern only public water systems, the Department cannot enforce standards for public water systems on privately owned wells, seeps and springs that do not meet the definition of a public water system; therefore, this comment is outside the scope of this final-form rulemaking.

Although the Department may not enforce public water system regulations on privately owned water systems, the Department often receives questions regarding privately owned wells. Information regarding well construction, drinking water testing and treatment, and other information are available on the Department's web site at https://www.dep.pa.gov/Citizens/My-Water/PrivateWells/pages/default.aspx.

Other comments beyond statutory and regulatory authority

Several comments submitted on the proposed rulemaking were outside the scope and authority of the act and Chapter 109 regulations and, therefore, cannot be addressed in this final-form rulemaking, including comments on requiring blood testing or health monitoring, reducing sources of PFAS and holding polluters responsible for cleaning up contamination.

G. *Benefits, Costs and Compliance*

Benefits

The PFOA and PFOS MCLs will apply to all 3,117 community, nontransient noncommunity and BVRB water systems in this Commonwealth. Of these, 1,905 are community water systems, serving a combined population of approximately 11.4 million residents of this Commonwealth; another 1,096 are nontransient noncommunity water systems serving approximately 507,000 persons.

The benefits associated with reductions of PFOA and PFOS in drinking water arise from a reduction in adverse human health effects. Exposure to PFOA is associated with adverse developmental effects (including neurobehavioral and skeletal effects) and exposure to PFOS is associated with adverse immune system impacts (including immune suppression). Benefits may also be derived through effects on customer actions to avoid exposure, such as a customer's purchase of bottled water or the installation and operation of home water treatment systems.

The benefits of MCLs can be presented as a percent improvement in public health protection as compared to the 2016 EPA HAL of 70 ng/L. Table 10 includes a summary of the percent improvement in public health protection for PFOA and PFOS at several levels.

Table 10. Percent Improvement in Health Protection as Compared to EPA's HAL

PFOA		*PFOS*	
Various Levels (ng/L)	*Percent Improvement in Health Protection as Compared to EPA HAL of 70 ng/L*	*Various Levels (ng/L)*	*Percent Improvement in Health Protection as Compared to EPA HAL of 70 ng/L*
35	56%	35	63%
20	80%	20	89%
14 (MCL)	90%	18 (MCL)	93%
12	93%	16	96%
10	96%	15	98%
8 (MCLG)	100%	14 (MCLG)	100%

The percentage improvement in health protection values for PFOA and PFOS are based on an assumption that there is a linear improvement in health protection between the 2016 EPA HAL and the DPAG MCLG. The amount of improvement is set such that it totals 100% between the 2016 EPA HAL and the DPAG MCLG. The equation for calculating percent improvement in health protection is established as follows:

Percent Improvement = $((\text{EPA HAL} - \text{MCLG})^{-1} \times 100) \times (\text{EPA HAL} - \text{Level "X"})$

As per the DPAG MCLG Report, PFOA has the potential to disrupt human development. The most sensitive developmental effects observed include neurobehavioral and skeletal effects. It is anticipated that these developmental effects have a measurable effect on the health of infants. The MCL for PFOA of 14 ng/L would be expected to improve health protection and lower the incidence of developmental effects by 90% compared with the 2016 EPA HAL of 70 ng/L.

The DPAG MCLG Report also found that PFOS has the potential to disrupt the immune system. The effects of immune suppression are anticipated to reduce the ability to resist infections, potentially increasing the risk, duration and severity of diseases. These immune effects from PFOS have a substantial effect on the health and economy of this Commonwealth. The MCL for PFOS of 18 ng/L would be expected to improve health protection and lower the incidence of immune suppression effects by 93% compared with the 2016 EPA HAL of 70 ng/L.

In 2022, the DPAG provided additional information on the health benefits achieved by these MCLs. In a report titled "Review of Proposed Maximum Contaminant Levels for PFOA and PFOS in Drinking Water for the Commonwealth of Pennsylvania," the DPAG concluded that the proposed MCLs are predicted to have a significant economic benefit to this Commonwealth because the MCLs will reduce health care problems associated with PFAS (DPAG, 2022).

To predict the value of health care benefits, the DPAG used two approaches—the value transfer method and the counterfactual method. The value transfer method applies and scales quantitative estimates of health care impact costs from one study site to another. The counterfactual method assumes that reduction in exposure to PFOA and PFOS from drinking water will result in a health care cost benefit equal to estimated health care costs attributable to the base exposures to PFOA and PFOS. Although each of these methods has their limitations, it is possible to estimate projected savings from reducing exposure to PFOA and PFOS.

The DPAG's health care analysis was broken down into three steps: (1) testing whether the selected MCL will result in hypothetical serum levels known to be associated with disease specific critical effects identified by the DPAG working group; (2) applying the counterfactual method to data derived from a study of a subpopulation of residents of this Commonwealth near a PFAS-contaminated site to estimate health care benefits for that group; and (3) deriving a value transfer estimate from other health care impact studies.

The DPAG reviewed several studies that examined the exposure response relationship between PFOA levels and low birth weight. The authors of the Malits study selected a maternal serum level of 3.1 ng/mL as a reference level (Malits 2018); below this level, the adverse health effects on low-birthweight infants would be reduced. The 3.1 ng/mL level also represents the upper limit of the lowest tertile in the study by Maisonet and colleagues (Maisonet 2012) and represents the point above which statistically significant associations have been demonstrated when median serum or plasma levels during pregnancy were above approximately 3.1 ng/mL (Maisonet 2012; Fei 2011; Wu 2012).

The DPAG utilized a serum PFAS calculator developed by Bartell to estimate blood serum concentrations of PFOA, based on an initial serum concentration and proposed levels of PFOA (Bartell 2017). The DPAG found that the model predicts that a woman of childbearing age would reach a steady-state PFOA serum level of 3.1 ng/mL if the consumed water was at the proposed MCL of 14 ng/L. See Figure 1. Furthermore, the Bartell calculator confirms that the proposed MCL of 14 ng/L for PFOA is protective and is consistent with the Department's analysis that the MCL represents a 90% improvement in blood serum levels compared to the serum level predicted at the EPA HAL of 70 ng/L (DPAG, 2022).

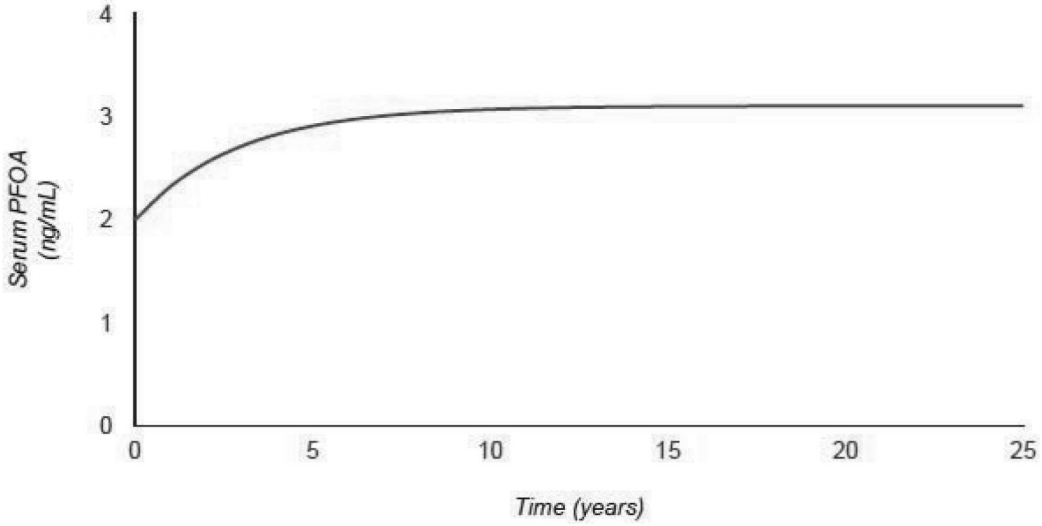
The DPAG conducted a similar analysis for PFOS using data from the Grandjean (2012) study. The method developed by Bartell predicts that in women of childbearing age, the PFOS MCL of 18 ng/L would result in a steady-state serum level of 7.2 ng/L, which is below the lower bound of interquartile range and the geometric mean in mothers in the Grandjean study. See Figure 2.

Figure 1: Steady-state PFOA level predicted in females childbearing age consuming water with PFOA of 14 ppt (from DPAG, 2022)

Serum PFAS Calculator for Adults:

Enter the following values, then click on the "submit" button:

1. Select the chemical you want to model: PFOA
2. Starting serum PFOA concentration (µg/L, ng/mL or ppb)
3. Two (2) is a typical value for an adult with no PFOA in his or her water.
4. PFOA concentration in drinking water (ng/L or ppt)
5. Enter zero (0) if drinking only bottled water, carbon-filtered water, or water treated by reverse osmosis. 14
6. Biological sex and menstrual status (optional): Female, premenopause or perimenopause (still having periods)



Starting serum PFOA concentration: 2 ng/mL
Water PFOA concentration: 14 ppt
Serum PFOA contribution from other ongoing exposures: 1.67 ng/mL
Water ingestion rate: 16.6 ml/kg/d
Volume of distribution: 0.17 L/kg
Half-life of PFOA in serum: 2 years
Steady-state ratio for serum:water concentrations: 102.91
Predicted steady-state serum PFOA concentration: 3.11 ng/mL

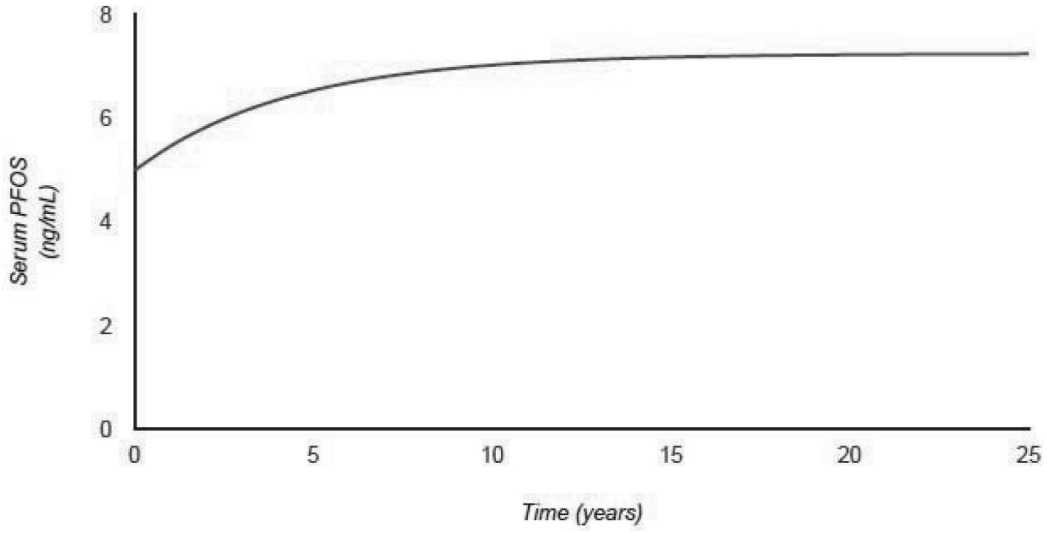
Calculator Version 1.2 by Sherman Lu and Scott Bartell.
Citation: Lu S, Bartell SM. Serum PFAS Calculator for Adults, Version 1.2, 2020, www.ics.uci.edu/~sbartell/pfascalc.html.

Figure 2: Steady-state PFOA level predicted in females childbearing age consuming water with PFOA of 14 ppt (from DPAG, 2022)

Serum PFAS Calculator for Adults:

Enter the following values, then click on the "submit" button:

1. Select the chemical you want to model: PFOS
2. Starting serum PFOS concentration (µg/L, ng/mL or ppb)
3. Five (5) is a typical value for an adult with no PFOS in his or her water.
4. PFOS concentration in drinking water (ng/L or ppt)
5. Enter zero (0) if drinking only bottled water, carbon-filtered water, or water treated by reverse osmosis.
6. Biological sex and menstrual status (optional): Female, premenopause or perimenopause (still having periods)



Starting serum PFOS concentration: 5 ng/mL
Water PFOS concentration: 18 ppt
Serum PFOS contribution from other ongoing exposures: 5.2 ng/mL
Water ingestion rate: 16.6 ml/kg/d
Volume of distribution: 0.23 L/kg
Half-life of PFOS in serum: 3 years
Steady-state ratio for serum:water concentrations: 114.09
Predicted steady-state serum PFOS concentration: 7.25 ng/mL

Calculator Version 1.2 by Sherman Lu and Scott Bartell.
Citation: Lu S, Bartell SM. Serum PFAS Calculator for Adults, Version 1.2, 2020, www.ics.uci.edu/~sbartell/pfascalc.html.

To summarize, the DPAG's review of PFAS blood serum levels at various PFAS concentrations in drinking water correlate well with the Department's assessment of at least 90% improvement of public health at the proposed MCLs.

In estimating the health care benefits for the MCLs, the DPAG noted that Malits (2018) estimated the total socioeconomic cost of PFOA-attributable low-birthweight births in the United States from 2003 through 2014 (over 11 years) was $13.7 billion. These costs included the direct hospital costs at the time of birth and lost economic productivity due to low-birthweight births being associated with longer-term outcomes such as lower lifetime earning potential. To determine what this would mean in this Commonwealth, the DPAG applied a value transfer method that assumes a scalable relationship between impacts of PFOA-attributable low-birthweight births quantified by Malits in the total United States population. Since 4.0% of the United States population lives in this Commonwealth, the total costs for the entire State-wide population due to low birthweight from PFOA exposure for the same period (2003—2014) are calculated to $548 million (approximately $637.58 million in 2022 dollars). To compare the costs and benefits to the Commonwealth's PWSs and the 11.9 million customers they serve, the DPAG estimated the total socioeconomic costs equate to $583 million in 2022 dollars. In other words, the PFOA MCL of 14 ng/L is estimated to result in health care cost savings of $583 million over a similar time period, or an average of $53 million annually.

The DPAG analyzed two additional studies to inform the estimated annual health care costs. In 2018, Nair studied communities near two former military bases in this Commonwealth that were exposed for several decades to PFAS through contaminated drinking water (Nair 2021). The population in that community was estimated to be 84,000. Serum PFAS levels were compared with the National averages for 2013-2014 and their relationships with demographic and exposure characteristics were analyzed. The average levels of PFOA and

PFOS among the study participants were 3.13 and 10.24 ng/mL, respectively. Overall, 75% and 81% of the study participants had levels exceeding the National average for PFOA (1.94 µg/L or ng/mL) and PFOS (4.99 µg/L or ng/mL), respectively. This study places these 2018 Commonwealth communities in the same broad category as the 2003 National Health and Nutrition Examination Survey data for the United States population. A similar value transfer analysis suggests that the total health care costs associated with PFOA exposure in these Commonwealth communities alone over a similar time period (11 years) would be $4.3 million in 2022 dollars. Assuming that PFAS levels fell in these Commonwealth communities in the same manner that they fell Nationally, the costs would average to $390,000 per year.

Finally, the DPAG reviewed a study by the Nordic Council of Ministers (2019) that estimated the annual monetized impact of elevated mortality due to PFAS exposure ranged from $3.5 billion to $5.7 billion for a total population of 20.7 million people. Adjusted for the 11.9 million residents of this Commonwealth served by public water, this produces a value transfer estimate of $2 billion to $3.3 billion. This suggests that PFAS contamination in drinking water may account for 2% to 3% of the total annual health care costs in this Commonwealth, which are estimated by the Kaiser Family Foundation at $120 billion annually (KFF 2022).

Compliance monitoring costs

Compliance monitoring cost estimates for this final-form rulemaking were determined based on a survey conducted of laboratories accredited in this Commonwealth for PFAS analysis by one or more of the analytical methods in this final-form rulemaking, as well as assumptions made based on an analysis of the occurrence data. According to lab survey results, the analytical cost for PFAS by either EPA Method 533, EPA Method 537 version 1.1 or EPA Method 537.1 varied greatly among the labs that responded, with a range of $325 to $750, and an average of $516, including the cost of analysis of the associated field reagent blank required by the methods for each sample site. This does not include an additional fee for sample collection, which also varied greatly among the labs offering that service; sample collection is approximately an additional $200 based on the survey.

Approximately half of the responding laboratories noted that they offer a cost reduction for reporting of fewer analytes than included in the method, which would provide a cost savings for systems since monitoring is required for only two analytes—PFOA and PFOS. Also, a few labs noted potential savings if there are no detections in the sample; the associated field blank would be extracted, but would not need to be analyzed, which would reduce the overall cost. A few labs also noted potential additional fees for PFAS-free blank water, overnight shipping costs for samples and Level 4 data reports if requested.

For compliance monitoring cost estimates, it was assumed that approximately half of all water systems will collect their own samples and half will utilize sample collection services provided by the laboratory. Therefore, an average cost of $616 per sample was used in the following compliance monitoring cost estimate calculations.

In this final-form rulemaking, initial quarterly monitoring for community and nontransient noncommunity systems serving a population of more than 350 persons begins January 1, 2024, and initial quarterly monitoring for community and nontransient noncommunity systems serving 350 or fewer persons begins January 1, 2025. This population breakdown was selected to evenly split initial monitoring across 2 years to ease laboratory capacity issues and allow small systems more time to prepare for compliance monitoring. Initial monitoring for BVRB systems begins January 1, 2024. Based on the number of PWSs and EPs in the Pennsylvania Drinking Water Information System (PADWIS) at the time of this final-form rulemaking, there are 1,885 EPs that will begin monitoring in year 1 (2024) and 1,900 that will conduct initial monitoring in year 2 (2025).

This final-form rulemaking requires repeat compliance monitoring on a quarterly basis for any EPs at which either PFOA or PFOS is detected at a level above its respective minimum reporting limit (MRL), including those EPs at which one or both MCLs are exceeded. If the quarterly repeat monitoring results are reliably and consistently below the MCLs, the frequency of repeat monitoring may be reduced from quarterly monitoring to annual monitoring. Based on the occurrence data, it is assumed that up to 34.9% of all EPs will have a detection of PFOA or PFOS, or both, at or above the relevant MRL; this equates to 658 EPs of the year 1 initial systems that will need to continue quarterly repeat monitoring in year 2, and 663 EPs of the year 2 initial systems that will need to continue quarterly repeat monitoring in year 3. The remaining systems (1,227 EPs in year 1 and 1,237 EPs in year 2) were assumed to conduct annual repeat monitoring in each year following the initial monitoring, but this overestimates the repeat monitoring requirements and costs after the initial monitoring because, for EPs where initial monitoring results do not detect PFOA or PFOS, the frequency of repeat monitoring is reduced from annual to once every 3 years.

In addition to and separate from the performance monitoring required by permit special condition, systems with EPs that exceed one or both MCLs may require treatment, which would require the system to conduct ongoing repeat compliance monitoring at least annually. Using the noncompliance rate of 7.4% from the occurrence data (as described in section D of this preamble), a total of 280 EPs are estimated to require ongoing repeat compliance monitoring: 139 EPs from initial year 1 and 141 EPs from initial year 2. However, this is likely an overestimate because: (1) systems may have options other than installing treatment to address concentrations of PFOA or PFOS, or both, above the relevant MCL; and (2) the occurrence data sampling predominately targeted sites near potential sources of PFAS contamination, so the exceedance rate in the occurrence data may overestimate the exceedance rate for other PWSs in this Commonwealth that were not included in the occurrence data. For total compliance monitoring cost estimates, the ongoing annual compliance monitoring for EPs where treatment is installed was assumed to begin in the third year of monitoring (year 3 or year 4 overall).

Using these assumptions (which likely overestimate the compliance monitoring requirements and costs for the reasons described previously) and an estimated average cost of $616 per sample, Table 11 summarizes the overall cost estimates for compliance monitoring costs in each of the first 4 years of rule implementation. Note that this estimate does not include performance monitoring costs.

Table 11. Compliance Monitoring Costs

	Total # EPs	*Quarterly Initial EPs*	*Annual Repeat EPs*	*Quarterly repeat EPs*	*Quarterly compliance monitoring cost*	*Annual compliance monitoring cost*	*Total yearly compliance monitoring cost*
Year 1	1885	1885	0	0	$4,644,640	$0	$4,644,640
Year 2	1900	1900	1227	658	$6,302,579	$755,915	$7,058,495
Year 3		0	3122	663	$1,633,878	$1,923,090	$3,556,969
Year 4		0	3785	0	$0	$2,331,560	$2,331,560

Based on these estimates, the average annual monitoring costs over the first 4 years are $4,397,916. Note that this average annual compliance monitoring cost estimate of approximately $4.4 million is less than the sum of the average annual compliance monitoring cost estimates presented in the cost-benefit analysis section of this preamble for PFOA ($2.9 million) and PFOS ($2.7 million). The reason for this difference in the average annual compliance monitoring cost estimates when considered for each individual contaminant (that is, PFOA and PFOS separately) compared with both contaminants together is that exceedances of the PFOA and PFOS MCLs are expected to co-occur at some sites. For instance, the occurrence data showed exceedance rates of the individual MCLs for PFOA and PFOS of 5.7% and 5.1%, respectively; however, the exceedance rate for the MCLs accounting for co-occurring exceedances was only 7.4% (not 10.8%, the sum of the exceedance rates for the MCLs considered individually). Since the laboratory analytical methods include both PFOA and PFOS, systems with exceedances of both MCLs will not have to collect separate samples for PFOA and PFOS, which results in some reduction in compliance monitoring costs for these systems compared with if each contaminant is considered separately. However, because PFOA and PFOS are each associated with different health effects and have different recommended MCLGs, the compliance monitoring cost estimates are presented separately for each contaminant in the cost-benefit analysis section of this preamble to inform the cost-benefit analysis for each MCL.

Treatment costs

Treatment cost estimates were determined based on a survey conducted of systems in this Commonwealth with existing PFAS treatment and of PFAS treatment manufacturers, a PFAS Case Study published by the American Water Works Association (AWWA, 2020) and from information provided by members of the Association of State Drinking Water Administrators. Costs were provided for GAC, anion exchange (IX) and reverse osmosis (RO). The RO costs were not included in the final cost estimates because, due to wastewater disposal requirements, the technology is currently impractical. Additionally, the costs for GAC, IX and RO provided from the vendors were excluded from the final cost estimates because they were limited to media costs and did not include the infrastructure requirements.

GAC and IX construction costs were based on a lead lag configuration where the first vessel (lead vessel) is capable of treating the entire flow and second vessel (lag vessel) is provided for polishing. Treatment costs were normalized to construction costs for treating 1 MGD.

As shown in Table 12, the average capital cost for the GAC treatment was $3,457,110 per MGD per EP with an average annual O&M cost of $171,970 per MGD per EP.

Table 12. GAC Treatment Costs

Treatment	*System*	*Capital Cost per MGD per EP*	*Annual O&M Cost per MGD per EP*
GAC	Vendor A	$343,000 *	$32,018
GAC	Vendor B	$535,000 *	$356,000
GAC	System A (2 GAC and 1 IX)	$3,125,000	$107,007
GAC	System B, Site 1	$1,675,347	$121,528
GAC	System B, Site 2	$2,454,259	$220,820
GAC	System B, Site 3	$2,433,333	$194,444
GAC	System C	$9,250,000	unknown
GAC	System D	$3,139,000	unknown
GAC	System E	$1,135,497	unknown
GAC	System F	$4,444,444	unknown
Average cost of GAC per MGD per EP		$3,457,110	$171,970

* Not included in calculations

As shown in Table 13, the average capital cost for the IX treatment was $3,284,360 per MGD per EP with an average annual O&M cost of $155,666 per MGD per EP.

Table 13. IX Treatment Costs

Treatment	*System*	*Capital Cost per MGD per EP*	*Annual O&M Cost per MGD per EP*
IX	Vendor A	$357,000 *	$59,361 *
IX	Vendor B	$500,000 *	$175,000
IX	Vendor D	No information	$159,722
IX	System G	$10,400,000	unknown
IX	System H	$3,333,000	unknown
IX	System I	$634,900	unknown
IX	System J	$1,128,000	unknown
IX	System K	$925,900	$132,275
Average cost of IX per MGD per EP		$3,284,360	$155,666

* Not included in calculations

The average capital costs of the GAC and IX treatment is $3,370,735 per MGD per EP with an average annual O&M costs $163,818 per MGD per EP.

To estimate annual treatment costs, the average capital cost of treatment installation of $3,370,735 per MGD per EP was annualized over 20 years at a 4% interest rate. This yields an estimated annualized capital cost of $248,025 per MGD per EP.

In addition, water systems that install treatment will need to conduct performance monitoring, to verify treatment efficacy. Using the average cost per sample of $616 and assuming a total of 36 performance monitoring samples per year—monthly samples at each of three locations (raw water, mid-point of treatment and finished water)—that is an additional annual cost of $22,176 per EP.

In the occurrence data, the percentage of EPs exceeding the MCLs for PFOA and PFOS was 5.7% and 5.1%, respectively; however, due to co-occurrence of PFOA and PFOS, some EPs that exceeded the MCL for PFOA also exceeded the MCL for PFOS. In the occurrence data, the percentage of EPs exceeding the MCL for PFOA or the MCL for PFOS, or both, was 7.4%. However, this exceedance rate may overestimate the exceedance rate for the other PWSs in this Commonwealth that were not sampled, because the occurrence data sampling predominately targeted sites near potential sources of PFAS contamination. Also, as treatment for PFOA and PFOS is the same, EPs exceeding both MCLs would not be required to install two different treatment systems; therefore, the estimated percentage of EPs requiring treatment is less than the combined percentage of systems exceeding either MCL in the occurrence data. Additionally, systems with MCL exceedances may have several options to address the contamination aside from installing treatment, including taking contaminated sources offline, making operational changes such as blending sources, or using alternate sources of supply (developing new sources or using purchased sources from a new interconnect). Recognizing that the MCL exceedance rates from the occurrence data may overestimate the proportion of systems that will need to install treatment to address MCL exceedances for the aforementioned reasons, the occurrence data provides the most relevant information currently available on the prevalence and levels of PFAS in PWSs in this Commonwealth. Using the 7.4% exceedance rate from the occurrence data to estimate how many of the larger universe of 3,785 EPs may require treatment to meet one or both MCLs produces an estimate of 280 EPs. At an average annualized treatment capital cost of $248,025 per MGD per EP, and assuming 280 EPs require treatment installed, the total estimated annual treatment costs are shown in Table 14.

Table 14. Total Estimated Annual Treatment Costs

Estimated average annualized treatment *capital* costs (per MGD per EP)	$248,025
Estimated average annual treatment *O&M* costs (per MGD per EP)	$163,818
Estimated average annual treatment *capital* + *O&M* costs (per MGD per EP)	$411,843
Estimated annual *performance monitoring* costs (per EP)	$22,167
Estimated # of EPs (of 3,785) that require treatment for one or both MCLs	280
Total estimated average annual treatment *capital* + *O&M* costs (per MGD)	$115,316,040
Total estimated annual *performance monitoring* costs	$6,206,760

Cost-benefit analysis

Following is a summary of the estimated costs and benefits associated with the MCL for PFOA of 14 ng/L. Treatment cost estimates are based on the costs to install and maintain treatment for a 1-MGD treatment plant. Cost estimates are based on the Department's survey of costs from vendors and systems that have installed PFAS treatment. This survey provided information that showed generally lower capital and operational costs for smaller systems and increased costs as the volume of water treated increases; however, capital costs can vary greatly based on site-specific needs. Because of this variability and the limited cost information from available systems, a linear model for cost determination may not be accurate. Smaller systems may be more expensive to treat on a per gallon basis. Some systems may need infrastructure upgrades above and beyond the cost of the PFAS treatment, such as new well pumps, booster pumps and buildings to house the treatment, whereas other systems may only need to purchase and install the PFAS treatment equipment and media.

- Estimated costs:

○ Estimated average annual compliance monitoring costs (@ $616/EP/Quarter) = $2.9 million

○ Estimated average annual treatment costs (average of GAC and IX) = $89.8 million per MGD + estimated annual performance monitoring costs = $4.8 million

• Estimated annual treatment capital costs, annualized over 20 years at 4% interest = $248,025 per MGD per EP × 218 EPs = $54.1 million per MGD

• Estimated annual treatment O&M costs = $35.7 million per MGD + estimated annual performance monitoring costs = $4.8 million

• Estimated annual treatment O&M costs = $163,818 per MGD per EP × 218 EPs = $35.7 million per MGD

• Estimated annual performance monitoring costs = $616 per sample per EP × 36 samples = $22,176 per EP × 218 EPs = $4.8 million

○ Estimated total annual costs = $89.8 million per MGD in treatment costs + $7.7 million in compliance monitoring and performance monitoring costs

• Estimated benefits:

○ 90% improvement in health protection as compared to 2016 EPA HAL of 70 ppt

○ Estimated health care cost savings of $53 million annually, including direct hospital costs at the time of birth and lost economic productivity due to low-birthweight births being associated with longer-term outcomes such as lower lifetime earning potential

Table 15 provides a comparison of costs and benefits for the MCL for PFOA of 14 ng/L, EPA's 2016 HAL of 70 ng/L and other values considered for the MCL.

Table 15. PFOA Comparison of Costs and Benefits

PFOA Annual Costs and Benefits Analysis								
Value (ng/L)	*Estimated # of EPs (of 3,785) > Value*	*Compliance Monitoring Costs (Millions)*	*Treatment O&M Costs*		*Treatment Capital Costs (Millions) per MGD* annualized over 20 years*	*Total Costs (Millions)*	*% Increase in Cost Compared to HAL*	*% Improvement in Health Protection Compared to HAL*
			*Treatment O&M Costs (Millions) per MGD**	*Performance Monitoring Costs (Millions)*				
HAL = 70	58	$2.46	$9.50	$1.29	$14.39	$27.63	0%	0%
35	78	$2.56	$12.78	$1.73	$19.35	$36.41	32%	56%
20	200	$2.73	$32.76	$4.44	$49.60	$89.53	224%	80%
MCL = 14	218	$2.89	$35.71	$4.83	$54.07	$97.51	253%	90%
12	270	$2.97	$44.23	$5.99	$66.97	$120.15	335%	93%
10	313	$3.07	$51.28	$6.94	$77.63	$138.92	403%	96%
MCLG = 8	400	$3.39	$65.53	$8.87	$99.21	$177.00	541%	100%

* For purposes of totaling annual costs, the costs that vary with design capacity (treatment O&M and treatment capital costs) were multiplied by a benchmark design capacity of 1 MGD.

In evaluating the costs and benefits, the Department's goal was to provide at least a 90% reduction in adverse health effects (a 90% improvement in health protection) when compared to the 2016 EPA HAL of 70 ng/L. This goal is consistent with several existing drinking water standards including the following standards:

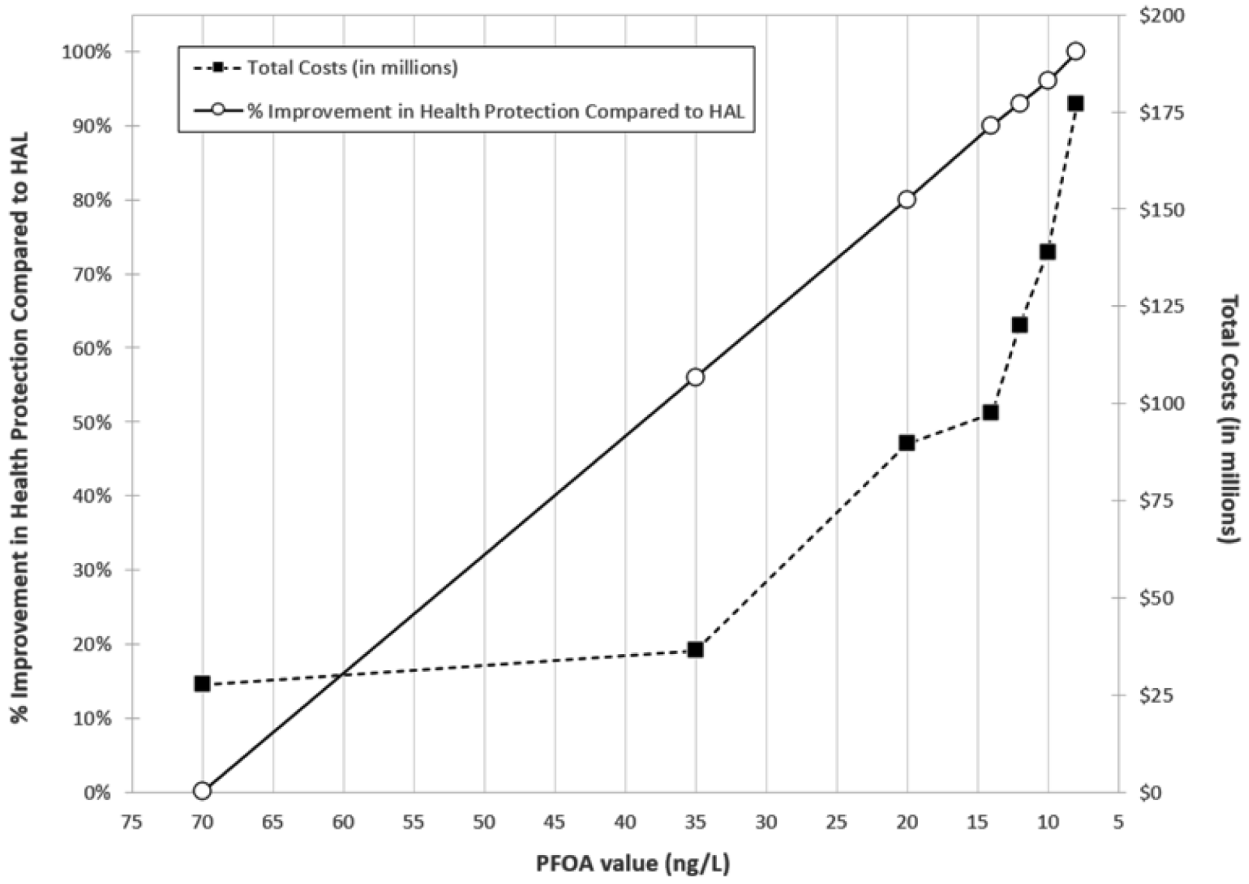
• the requirement to achieve at least a 90% inactivation of *Giardia* cysts using disinfection processes within a filtration plant (§ 109.202(c)(1)(ii) regarding treatment technique requirements for pathogenic bacteria, viruses and protozoan cysts);

• the use of the 90th percentile lead and copper levels when determining compliance with the lead and copper action levels of 0.015 mg/L and 1.3 mg/L, respectively (§ 109.1102(a) (relating to action levels and treatment technique requirements) regarding action levels for lead and copper), and

• the requirement to meet the filtered water turbidity standards in 95% of measurements taken each month (§ 109.202(c)(1)(i)).

As shown in Table 15 and Figure 3, additional improvement in public health benefits at PFOA values lower than the MCL of 14 ng/L would require increasingly steep costs. For example, compared with the MCL of 14 ng/L, an MCL value of 10 ng/L is estimated to achieve an additional 6% increase at an additional annual cost of approximately $41.4 million (Table 15, Figure 3), which is a rate of approximately $7 million in additional annual costs for every additional 1% of benefits. Compared with the 2016 EPA HAL, the MCL of 14 ng/L is estimated to achieve a 90% improvement in public health benefits at an additional annual cost of roughly $70 million, which is a rate of approximately $0.8 million in additional annual costs for every additional 1% of benefits.

Figure 3. Annual Total Costs and Benefits (% Health Protection Improvement) at Various PFOA levels



For the aforementioned reasons, the Board is setting an MCL for PFOA of 14 ng/L, which strikes an appropriate balance between the benefits (90% improvement in public health) and costs (253% increase in costs) when compared to the benefits and costs associated with meeting the 2016 EPA HAL of 70 ng/L. Additionally, the total estimated treatment and monitoring costs are offset by the total estimated health care cost savings of at least $53 million annually.

Following is a summary of the estimated costs and benefits associated with the MCL for PFOS of 18 ng/L. Treatment cost estimates are based on the costs to install and maintain treatment for a 1-MGD treatment plant. The actual costs would be expected to be less for a treatment plant with a smaller design capacity. Cost estimates are based on the Department's survey of costs from vendors and systems that have installed PFAS treatment. This survey provided information that showed generally lower capital and operational costs for smaller systems and increased costs as the volume of water treated increases; however, capital costs can vary greatly based on site-specific needs. Because of this variability and the limited cost information from available systems, a linear model for cost determination may not be accurate. Smaller systems may be more expensive to treat on a per gallon basis. Some systems may need infrastructure upgrades above and beyond the cost of the PFAS treatment, such as new well pumps, booster pumps and buildings to house the treatment, whereas other systems may only need to purchase and install the PFAS treatment equipment and media.

- Estimated costs:

○ Estimated average annual compliance monitoring costs (@ $616/EP/Quarter) = $2.7 million

o Estimated average annual treatment costs (average of GAC and IX) = $78.7 million per MGD + estimated annual performance monitoring costs = $4.2 million

- Estimated annual treatment capital costs, annualized over 20 years at 4% interest = $$248,025 per MGD per EP × 191 EPs = $47.4 million per MGD

- Estimated annual treatment O&M costs = $31.3 million per MGD + estimated annual performance monitoring costs = $4.2 million

- Estimated annual treatment O&M costs = $163,818 per MGD per EP × 191 EPs = $31.3 million per MGD

• Estimated annual performance monitoring costs = $616 per sample per EP × 36 samples = $22,176 per EP × 191 EPs = $4.2 million

○ Estimated total annual costs = $78.7 million per MGD in treatment costs + $6.9 million in compliance monitoring and performance monitoring costs

• Estimated benefits:

○ 93% improvement in health protection as compared to 2016 EPA HAL of 70 ppt

Table 16 provides a comparison of costs and benefits for the MCL for PFOS of 18 ng/L, EPA's 2016 HAL of 70 ng/L and other values considered for the MCL.

Table 16. PFOS Comparison of Costs and Benefits

PFOS Annual Costs and Benefits Analysis								
Value (ng/L)	*Estimated # of EPs (of 3785) > Value*	*Compliance Monitoring Costs (Millions)*	*Treatment O&M Costs*		*Treatment Capital Costs (Millions) per MGD* annualized over 20 years*	*Total Costs (Millions)*	*% Increase in Cost Compared to HAL*	*% Improvement in Health Protection Compared to HAL*
			*Treatment O&M Costs (Millions) per MGD**	*Performance Monitoring Costs (Millions)*				
HAL = 70	96	$2.57	$15.73	$2.13	$23.81	$44.24	—	—
35	148	$2.64	$24.25	$3.28	$36.71	$66.87	51%	63%
20	183	$2.70	$29.98	$4.06	$45.39	$82.13	86%	89%
MCL = 18	191	$2.70	$31.29	$4.24	$47.37	$85.60	94%	93%
16	200	$2.73	$32.76	$4.44	$49.60	$89.53	102%	96%
15	200	$2.81	$32.76	$4.44	$49.60	$89.61	103%	98%
MCLG = 14	200	$2.88	$32.76	$4.44	$49.60	$89.68	103%	100%

* For purposes of totaling annual costs, the costs that vary with design capacity (treatment O&M and treatment capital costs) were multiplied by a benchmark design capacity of 1 MGD.

In evaluating the costs and benefits, the Department's goal was to provide at least a 90% reduction in adverse health effects (a 90% improvement in health protection) when compared to the 2016 EPA HAL of 70 ng/L. This goal is consistent with several existing drinking water standards including the following standards:

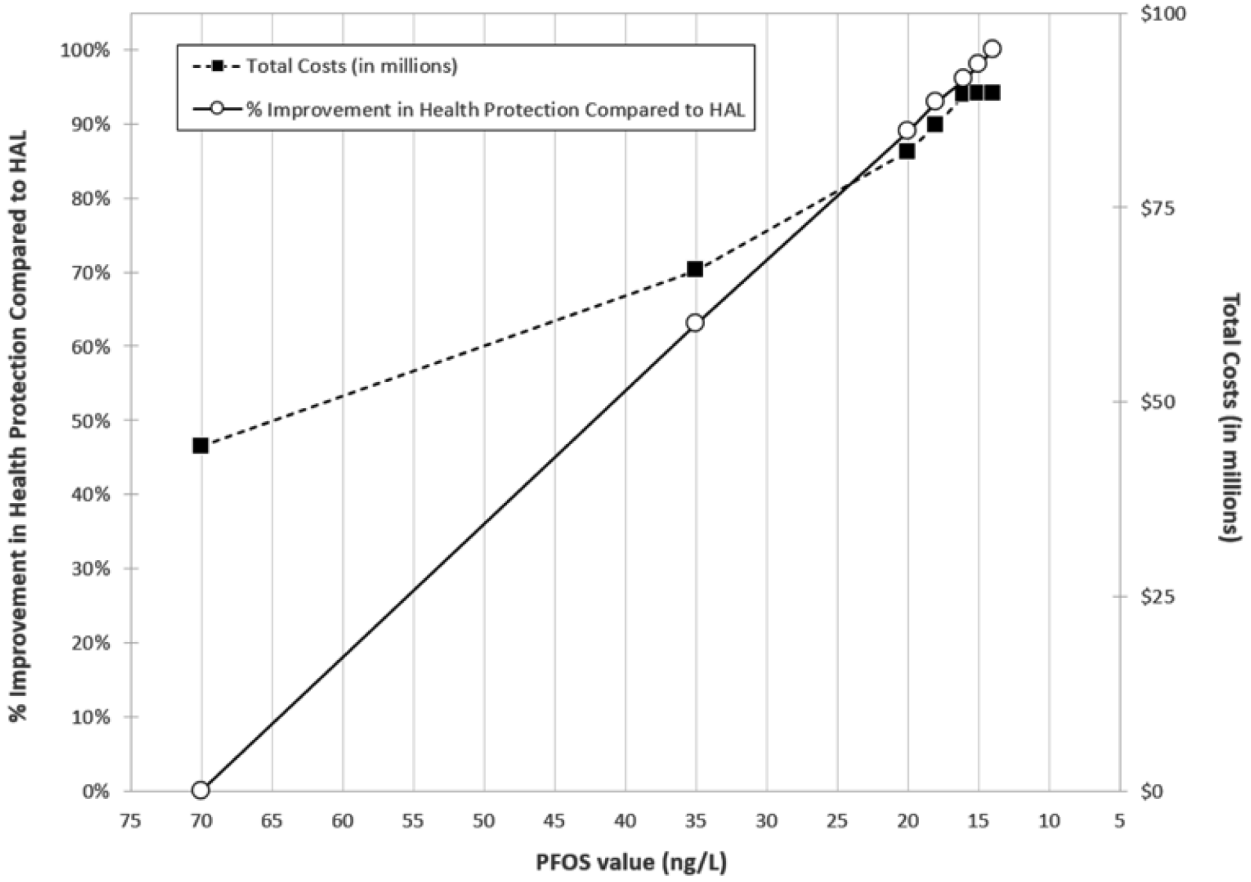
• the requirement to achieve at least a 90% inactivation of Giardia cysts using disinfection processes within a filtration plant (§ 109.202(c)(1)(ii)) regarding treatment technique requirements for pathogenic bacteria, viruses and protozoan cysts;

• the use of the 90th percentile lead and copper levels when determining compliance with the lead and copper action levels of 0.015 mg/L and 1.3 mg/L, respectively (§ 109.1102(a)), and

• the requirement to meet the filtered water turbidity standards in 95% of measurements taken each month (§ 109.202(c)(1)(i)).

As shown in Table 16 and Figure 4, additional improvement in public health benefits at PFOS values lower than the MCL of 18 ng/L would require increasingly steep costs. For example, compared with the MCL of 18 ng/L, an MCL value of 16 ng/L is estimated to achieve an additional 3% increase at an additional annual cost of approximately $3.9 million (Table 16, Figure 4), which is a rate of approximately $1.3 million in additional annual costs for every additional 1% of benefits. Compared with the 2016 EPA HAL, the MCL of 18 ng/L is estimated to achieve a 93% improvement in public health benefits at an additional annual cost of roughly $41.4 million, which is a rate of approximately $0.4 million in additional annual costs for every additional 1% of benefits.

Figure 4. Annual Total Costs and Benefits (% Health Protection Improvement) at Various PFOS levels



For the aforementioned reasons, the Board is setting an MCL for PFOS of 18 ng/L, which strikes a balance between the benefits (93% improvement in public health) and costs (94% increase in costs) when compared to the benefits and costs associated with meeting the 2016 EPA HAL of 70 ng/L. Additionally, the total estimated treatment and monitoring costs are offset by the total estimated health care cost savings of at least $53 million annually.

Compliance assistance plan

The Department's Safe Drinking Water Program utilizes Pennsylvania Infrastructure Investment Authority (PENNVEST) programs to offer financial assistance to eligible PWSs. This assistance is in the form of a low-interest loan, with some augmenting grant funds for hardship cases. Eligibility is based upon factors such as public health impact, compliance necessity and project/operational affordability.

In addition to the standard funding mentioned previously, PENNVEST approved an additional funding program in 2021 under authority of the act of November 27, 2019 (P.L. 695, No. 101). The PENNVEST PFAS Remediation Program is designed as an annual funding opportunity to aid in the remediation and elimination of PFAS in PWSs. In 2021, approximately $25 million was made available for this grant program.

On November 15, 2021, the IIJA was signed into Federal law. One component of the legislation is $4 billion Nationally in DWSRF moneys for projects to address emerging drinking water contaminants like PFAS and $5 billion Nationally in grants to small and disadvantaged communities for projects addressing emerging drinking water contaminants like PFAS. Over 5 years, the Commonwealth's allocation of these IIJA funds is expected to be $116 million in DWSRF emerging contaminants funds and an additional $140.5 million in funding for projects addressing emerging drinking water contaminants in small and disadvantaged communities, for a total of $256.5 million.

The Department's Safe Drinking Water Program has established a network of regional and Central Office training staff that is responsive to identifiable training needs. The target audience in need of training may be either program staff or the regulated community.

In addition to this network of training staff, the Department's Bureau of Safe Drinking Water has staff dedicated to providing both training and technical outreach support services to PWS owners and operators. The Department's web site also provides timely and useful information for treatment plant operators.

Paperwork requirements

New forms are not required for implementation of these amendments.

H. *Sunset Review*

This final-form rulemaking will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the regulations effectively fulfill the goals for which they were intended.

I. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on February 15, 2022, the Department submitted a copy of the notice of proposed rulemaking, published at 52 Pa.B. 1245, and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the Senate and House Environmental Resources and Energy Committees for review and comment.

Under section 5(c) of the Regulatory Review Act (71 P.S. § 745.5(c)), IRRC and the Committees were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing this final-form rulemaking, the Department has considered all comments from IRRC, the House and Senate Committees and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on November 16, 2022, this final-form rulemaking was deemed approved by the House and Senate Committees. Under section 5.1(e) of the Regulatory Review Act, IRRC met on November 17, 2022, and approved this final-form rulemaking.

J. *Findings of the Board*

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202), referred to as the Commonwealth Documents Law, and regulations promulgated thereunder at 1 Pa. Code §§ 7.1 and 7.2 (relating to notice of proposed rulemaking required; and adoption of regulations).

(2) A public comment period was provided as required by law and all comments were considered.

(3) This final-form rulemaking does not enlarge the purpose of the proposed rulemaking published at 52 Pa.B. 1245.

(4) These regulations are necessary and appropriate for administration and enforcement of the authorizing acts identified in section C of this order.

K. *Order of the Board*

The Board, acting under the authorizing statutes, orders that:

(a) The regulations of the Department, 25 Pa. Code Chapter 109, are amended by amending §§ 109.1, 109.202, 109.301, 109.303, 109.304, 109.411, 109.416, 109.503, 109.602, 109.701, 109.1003 and 109.1403 to read as set forth in Annex A, with ellipses referring to the existing text of the regulations.

(b) The Chairperson of the Board shall submit this final-form rulemaking to the Office of General Counsel and the Office of Attorney General for review and approval as to legality and form, as required by law.

(c) The Chairperson of the Board shall submit this final-form rulemaking to IRRC and the Senate and House Environmental Resources and Energy Committees as required by the Regulatory Review Act (71 P.S. §§ 745.1—745.14).

(d) The Chairperson of the Board shall certify this final-form rulemaking and deposit it with the Legislative Reference Bureau, as required by law.

(e) This final-form rulemaking shall take effect immediately upon publication in the *Pennsylvania Bulletin*.

RAMEZ ZIADEH, P.E.,
Acting Chairperson

(*Editor's Note*: See 52 Pa.B. 7487 (December 3, 2022) for IRRC's approval order.)

Fiscal Note: Fiscal Note 7-569 remains valid for the final adoption of the subject regulations.

Annex A

TITLE 25. ENVIRONMENTAL PROTECTION

PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION

Subpart C. PROTECTION OF NATURAL RESOURCES

ARTICLE II. WATER RESOURCES

CHAPTER 109. SAFE DRINKING WATER

Subchapter A. GENERAL PROVISIONS

§ 109.1. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

* * * * *

Bulk water hauling system—A public water system which provides water piped into a carrier vehicle and withdrawn by a similar means into the user's storage facility or vessel. The term includes, but is not limited to, the sources of water, treatment, storage or distribution facilities. The term does not include a public water system which provides only a source of water supply for a bulk water hauling system.

CASRN—Chemical Abstracts Service Registry Number.

CCR—Consumer Confidence Report—An annual water quality report that community water systems deliver to their customers, as described in § 109.416 (relating to CCR requirements).

* * * * *

Flowing stream—A course of running water flowing in a definite channel.

GAC—Granular Activated Carbon—A highly porous adsorbent carbon material produced by heating organic matter that can absorb various dissolved chemicals in the water.

GAC10—A granular activated carbon filter bed with an empty bed contact time of 10 minutes based on average daily flow and a carbon reactivation frequency of every 180 days, except that the reactivation frequency for GAC10 used as a BAT shall be 120 days.

* * * * *

MCL—Maximum Contaminant Level—The maximum permissible level of a contaminant in water which is delivered to a user of a public water system, and includes the primary and secondary MCLs established under the Federal act, and MCLs adopted under the act.

MCLG—Maximum Contaminant Level Goal—

(i) The maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, and which allows an adequate margin of safety.

(ii) The term includes the MCLGs established under the Federal act and MCLGs adopted under the act.

(iii) Maximum contaminant level goals are nonenforceable health goals.

MDL—Method Detection Limit—The minimum measured concentration of a substance that can be reported with 99% confidence that the measured concentration is distinguishable from method blank results.

MRDL—Maximum Residual Disinfectant Level—The maximum permissible level of a disinfectant added for water treatment that may not be exceeded at the consumer's tap without an unacceptable possibility of adverse health effects. The consumer's tap means the entry point for bottled water and vended water systems, retail water facilities and bulk water hauling systems.

MRL—Minimum Reporting Level—The minimum quantitation limit that can practically and consistently be achieved, with 95% confidence, by capable analysts at 75% or more of laboratories using a specified analytical method.

Membrane filtration—

(i) A pressure or vacuum driven separation process in which particulate matter larger than 1 micrometer is rejected by an engineered barrier, primarily through a size-exclusion mechanism, and which has a measurable removal efficiency of a target organism that can be verified through the application of a direct integrity test.

(ii) The term includes the common membrane technologies of microfiltration, ultrafiltration, nanofiltration and reverse osmosis.

Microorganism—Any of a number of unicellular, multicellular or colonial bacteria, fungi, protozoa, archaea or viruses whose individuals are too small to be seen by the human eye without magnification.

* * * * *

PDWEP—Guidelines for Public Drinking Water Equipment Performance issued by NSF.

PFAS—Perfluoroalkyl and polyfluoroalkyl substances.

PFOA—Perfluorooctanoic acid—CASRN 335-67-1.

PFOS—Perfluorooctanesulfonic acid—CASRN 1763-23-1.

Performance evaluation sample—A reference sample provided to a laboratory for the purpose of demonstrating that the laboratory can successfully analyze the sample within the limits of performance specified by the Department. The true value of the concentration of the reference material is unknown to the laboratory at the time of the analysis.

Person—An individual, partnership, association, company, corporation, municipality, municipal authority, political subdivision, or an agency of Federal or State government. The term includes the officers, employees and agents of a partnership, association, company, corporation, municipality, municipal authority, political subdivision, or an agency of Federal or State government.

* * * * *

Recycle flows—Any water, solid or semi-solid generated by a conventional or direct filtration plant's treatment process and residual treatment processes that is returned to the plant's treatment process.

Reliably and consistently below the MCL—

(i) For VOCs, SOCs, IOCs (with the exception of nitrate and nitrite) and PFAS, this means that each sample result is less than 80% of the MCL.

(ii) For nitrate and nitrite, this means that each sample result is less than 50% of the MCL.

* * * * *

Subchapter B. MCLs, MRDLs OR TREATMENT TECHNIQUE REQUIREMENTS

§ 109.202. State MCLs, MRDLs and treatment technique requirements.

(a) *Primary MCLs, MRDLs and treatment technique requirements.*

* * * * *

(3) A public water system that is installing granular activated carbon or membrane technology to comply with the MCL for TTHMs, HAA5, chlorite (where applicable) or bromate (where applicable) may apply to the Department for an extension of up to 24 months past the applicable compliance date specified in the Federal regulations, but not beyond December 31, 2003. In granting the extension, the Department will set a schedule for compliance and may specify any interim measures that the Department deems necessary. Failure to meet the schedule or interim treatment requirements constitutes a violation of National Primary Drinking Water Regulations.

(4) Other MCLs.

(i) *Effective dates.* The MCLGs and MCLs in subparagraph (ii)(A)—(B) are effective on January 14, 2023.

(ii) The MCLGs and MCLs for PFAS are:

CASRN	*Contaminant*	*MCLG (mg/L)*	*MCL (mg/L)*	*MCLG (ng/L)*	*MCL (ng/L)*
(A) 335-67-1	PFOA	0.000008	0.000014	8	14
(B) 1763-23-1	PFOS	0.000014	0.000018	14	18

(b) *Secondary MCLs.*

* * * * *

Subchapter C. MONITORING REQUIREMENTS

§ 109.301. General monitoring requirements.

Public water suppliers shall monitor for compliance with MCLs, MRDLs and treatment technique requirements in accordance with the requirements established by the EPA under the National Primary Drinking Water Regulations, 40 CFR Part 141 (relating to National Primary Drinking Water Regulations), except as otherwise established by this chapter unless increased monitoring is required by the Department under § 109.302 (relating to special monitoring requirements). Alternative monitoring requirements may be established by the Department and may be implemented in lieu of monitoring requirements for a particular National Primary Drinking Water Regulation if the alternative monitoring requirements are in conformance with the Federal act and regulations. The monitoring requirements shall be applied as follows:

* * * * *

(2) *Performance monitoring for unfiltered surface water and GUDI.* A public water supplier using unfiltered surface water or GUDI sources shall conduct the following source water and performance monitoring requirements on an interim basis until filtration is provided, unless increased monitoring is required by the Department under § 109.302:

(i) Except as provided under subparagraphs (ii) and (iii), a public water supplier:

(A) Shall perform *E. coli* or total coliform density determinations on samples of the source water immediately prior to disinfection. Regardless of source water turbidity, the minimum frequency of sampling for total coliform or *E. coli* determinations may be no less than the following:

System Size (People)	*Samples/Week*
<500	1
500—3,299	2
3,300—10,000	3
10,001—25,000	4
25,001 or more	5

(B) Shall measure the turbidity of a representative grab sample of the source water immediately prior to disinfection as follows until August 19, 2019:

(I) For systems that operate continuously, at least once every 4 hours that the system is in operation, except as provided in clause (C).

(II) For systems that do not operate continuously, at start-up, at least once every 4 hours that the system is in operation, and also prior to shutting down the plant, except as provided in clause (C).

(C) May substitute continuous turbidity monitoring for grab sample monitoring until August 19, 2019, if it validates the continuous measurement for accuracy on a regular basis using a procedure specified by the manufacturer. At a minimum, calibration with an EPA-approved primary standard shall be conducted at least quarterly.

(D) Shall continuously monitor and record the turbidity of the source water immediately prior to disinfection beginning August 20, 2019, using an analytical method specified in 40 CFR 141.74(a) and record the results at least every 15 minutes while the source is operating. If there is a failure in the continuous turbidity monitoring or recording equipment, or both, the supplier shall conduct grab sampling or manual recording, or both, every 4 hours in lieu of continuous monitoring or recording. The public water supplier shall notify the Department within 24 hours of the equipment failure. Grab sampling or manual recording may not be substituted for continuous monitoring for longer than 5 working days after the equipment fails. The Department will consider case-by-case extensions of the time frame to comply if the water supplier provides written documentation that it was unable to repair or replace the malfunctioning equipment within 5 working days due to circumstances beyond its control.

(E) Shall continuously monitor and record the residual disinfectant concentration required under § 109.202(c)(1)(iii) of the water being supplied to the distribution system and record the lowest value for each day. If a public water system's continuous monitoring or recording equipment fails, the public water supplier may, upon notification of the Department under § 109.701(a)(3), substitute grab sampling or manual recording, or both, every 4 hours in lieu of continuous monitoring. Grab sampling or manual recording may not be substituted for continuous monitoring for longer than 5 days after the equipment fails.

(F) Until April 28, 2019, shall measure the residual disinfectant concentration at representative points in the distribution system no less frequently than the frequency required for total coliform sampling for compliance with the MCL for microbiological contaminants.

(G) Beginning April 29, 2019, shall measure and record the residual disinfectant concentration at representative points in the distribution system in accordance with a sample siting plan as specified in § 109.701(a)(8) and as follows:

(I) A public water supplier shall monitor the residual disinfectant concentration at the same time and from the same location that a total coliform sample is collected as specified in paragraph (3)(i) and (ii). Measurements taken under this subclause may be used to meet the requirements under subclause (II).

(II) A public water supplier shall monitor the residual disinfectant concentration at representative locations in the distribution system at least once per week.

(III) A public water supplier that does not maintain the minimum residual disinfectant concentration specified in § 109.710 at one or more sample sites shall include those sample sites in the monitoring conducted the following month.

(IV) Compliance with the minimum residual disinfectant concentration shall be determined in accordance with § 109.710.

(V) A public water system may substitute online residual disinfectant concentration monitoring and recording for grab sample monitoring and manual recording if it validates the online measurement for accuracy in accordance with § 109.304.

(ii) Until August 19, 2019, for a public water supplier serving 3,300 or fewer people, the Department may reduce the residual disinfectant concentration monitoring for the water being supplied to the distribution system to a minimum of 2 hours between samples at the grab

sampling frequencies prescribed as follows if the historical performance and operation of the system indicate the system can meet the residual disinfectant concentration at all times:

System Size (People)	*Samples / Week*
<500	1
500—1,000	2
1,001—2,500	3
2,501—3,300	4

If the Department reduces the monitoring, the supplier shall nevertheless collect and analyze another residual disinfectant measurement as soon as possible, but no longer than 4 hours from any measurement which is less than the residual disinfectant concentration approved under § 109.202(c)(1)(iii).

(iii) Until August 19, 2019, for a public water supplier serving fewer than 500 people, the Department may reduce the source water turbidity monitoring to one grab sample per day, if the historical performance and operation of the system indicate effective disinfection is maintained under the range of conditions expected to occur in the system's source water.

(*Editor's Note*: Section 109.301(2)(iv)—(iii) text as published at 52 Pa.B. 1245 (February 26, 2022) is deleted since it is duplicated in the *Pennsylvania Code* due to a previous printing error. The text of these serial pages can be found at (393259) and (391315) to (391317).)

(3) *Monitoring requirements for coliforms.* Public water systems shall determine the presence or absence of total coliforms for each routine or check sample; and, the presence or absence of *E. coli* for a total coliform positive sample in accordance with analytical techniques approved by the Department under § 109.304 (relating to analytical requirements). A system may forego *E. coli* testing on a total coliform-positive sample if the system assumes that any total coliform-positive sample is also *E. coli*-positive. A system which chooses to forego *E. coli* testing shall, under § 109.701(a)(3), notify the Department within 1 hour after the water system learns of the violation or the situation, and shall provide public notice in accordance with § 109.408 (relating to Tier 1 public notice—categories, timing and delivery of notice) if there is a violation of the *E. coli* MCL as set forth in subparagraph (iv).

* * * * *

(6) *Monitoring requirements for SOCs (pesticides and PCBs).* Community water systems and nontransient noncommunity water systems shall monitor for compliance with the MCLs for SOCs established by the EPA under 40 CFR 141.61(c). The monitoring shall be conducted according to the requirements established by the EPA under 40 CFR 141.24(h), incorporated herein by reference except as modified by this chapter.

* * * * *

(vii) *Waivers.* A waiver will be granted to a public water supplier from conducting the initial compliance monitoring or repeat monitoring, or both, for an SOC based on documentation provided by the public water supplier and a determination by the Department that the criteria in clause (B), (C) or (D) has been met. A waiver is effective for one compliance period and may be renewed in each subsequent compliance period. If the Department has not granted a use waiver in accordance with clause (B), the public water supplier is responsible for submitting a waiver application and renewal application to the Department for review in accordance with clause (B), (C) or (D) for specific entry points. Waiver applications will be evaluated relative to the vulnerability assessment area described in clause (A) and the criteria in clause (B), (C) or (D). Entry points at which treatment has been installed to remove an SOC are not eligible for a monitoring waiver for the SOCs for which treatment has been installed.

(A) *Vulnerability assessment area for SOCs including dioxin and PCBs.*

(I) For groundwater or GUDI entry points, the vulnerability assessment area shall consist of wellhead protection area Zones I and II as defined under § 109.1.

(II) For surface water entry points, the vulnerability assessment area shall consist of surface water intake protection area Zones A and B as defined under § 109.1.

(B) *Use waivers.* A use waiver will be granted by the Department for contaminants which the Department has determined have not been used, stored, manufactured, transported or disposed of in this Commonwealth, or portions of this Commonwealth. A use waiver specific to a particular entry point requires that an SOC was not used, stored, manufactured, transported or disposed of in the vulnerability assessment area. If use waiver criteria cannot be met, a public water supplier may apply for a susceptibility waiver.

* * * * *

(8) *Monitoring requirements for public water systems that obtain finished water from another public water system.*

* * * * *

(iii) Consecutive water suppliers may be exempt from conducting monitoring for the MCLs for VOCs, SOCs, IOCs, radionuclides and PFAS if the public water system from which the finished water is obtained complies with paragraphs (5)—(7), (14) and (16) and is in compliance with the MCLs, except that asbestos monitoring is required in accordance with subparagraph (ii).

* * * * *

(9) *Monitoring requirements for POE devices.* A public water supplier using a POE device shall, in addition to the monitoring requirements specified in paragraphs (1)—(8), (10)—(16) and Subchapter K (relating to lead and copper), conduct monitoring on the devices installed. As a minimum, the monitoring shall include the MCLs for which the POE device is intended to treat and monthly microbiological monitoring. The Department may allow the water supplier to reduce the frequency of microbiological monitoring based upon historical performance. Except for microbiological contaminants, monitoring shall be performed quarterly on 25% of the installed POE devices with the locations rotated so that each device is monitored at least once annually, unless increased monitoring is required by the Department under § 109.302.

* * * * *

(11) *Monitoring requirements for entry points that do not provide water continuously.* Entry points from which water is not provided during every quarter of the year shall monitor in accordance with paragraphs (5)—(7), (14) and (16), except that monitoring is not required during a quarter when water is not provided to the public, unless special monitoring is required by the Department under § 109.302.

* * * * *

(15) *Monitoring requirements for reserve entry points and entry points supplied by one or more reserve sources.* Beginning August 20, 2019, a water supplier using reserve sources or reserve entry points as defined and identified in the comprehensive monitoring plan in § 109.718(a) (relating to comprehensive monitoring plan) shall:

(i) Monitor reserve entry points at the initial frequencies specified in paragraphs (5)—(7), (14) and (16).

(ii) Monitor permanent entry points at the initial frequencies specified in paragraphs (5)—(7), (14) and (16) while the entry point is receiving water from a reserve source.

(iii) Conduct special monitoring as required by the Department under § 109.302.

(16) *Monitoring requirements for PFAS.* Community water systems and nontransient noncommunity water systems shall monitor for compliance with the MCLs for PFAS established under § 109.202(a).

(i) *Initial monitoring.* Initial monitoring shall consist of 4 consecutive quarterly samples at each entry point in accordance with the following monitoring schedule:

(A) Systems serving more than 350 persons shall begin monitoring during the quarter beginning January 1, 2024.

(B) Systems serving 350 or fewer persons shall begin monitoring during the quarter beginning January 1, 2025.

(C) Upon request, a system required to conduct monitoring under the Fifth Unregulated Contaminant Monitoring Rule (UCMR 5), specified in 40 CFR Part 141, may upon written approval from the Department modify the initial monitoring period required under clause (A) or (B) to coincide with UCMR 5.

(D) Systems that add new sources to new or existing entry points on or after the applicable dates in clauses (A) and (B), shall conduct initial monitoring according to this clause. An entry point with one or more new sources shall be monitored for 4 consecutive quarters, beginning the first full quarter the entry point begins serving the public.

(ii) *Repeat monitoring for PFAS that are detected.* For entry points at which a PFAS is detected at a level equal to or greater than its corresponding MRL as defined in § 109.304(f), then:

(A) Monitoring for the detected PFAS shall be conducted quarterly, beginning the quarter following the detection, until reduced monitoring is granted in accordance with this subparagraph.

(B) The Department may decrease the quarterly monitoring requirement specified in clause (A) if it has determined that monitoring results are reliably and consistently below the MCL. The Department will not make this determination until the water system obtains results from a minimum of four consecutive quarterly samples that are reliably and consistently below the MCL.

(C) If the Department determines that the monitoring results are reliably and consistently below the MCL, the Department may allow the system to monitor annually. Systems which monitor annually shall monitor during the quarter that previously yielded the highest analytical result, or as specified by the Department.

(iii) *Repeat monitoring for PFAS that are not detected.* For entry points at which a PFAS is not detected during initial monitoring in accordance with subparagraph (i), required monitoring for the PFAS not detected is reduced to one sample per entry point during each subsequent compliance period. This reduced monitoring shall be conducted in the same year as reduced monitoring granted for VOCs under paragraph (5)(iv)(B) and SOCs under paragraph (6)(iii) as specified by the Department.

(iv) *Repeat monitoring for PFAS with MCL exceedances.* For entry points at which a PFAS MCL is exceeded, monitoring for the exceeding PFAS shall be conducted quarterly, beginning the quarter following the exceedance. Quarterly monitoring shall continue until a minimum of four consecutive quarterly samples shows the system is in compliance as specified in subparagraph (ix) and the Department determines the system is reliably and consistently below the MCL. If the Department determines that the system is in compliance and is reliably and consistently below the MCL, the Department may allow the system to monitor in accordance with subparagraph (ii)(C).

(v) *Confirmation samples.* A confirmation sample shall be collected and analyzed for each of the PFAS detected in exceedance of its MCL during annual or less frequent compliance monitoring. The confirmation sample shall be collected within 2 weeks of notification from the accredited laboratory performing the analysis that an MCL has been exceeded.

(vi) *Monitoring for entry points with PFAS removal treatment.* The reduced monitoring option in subparagraph (iii) does not apply to entry points at which treatment has been installed for PFAS removal. Compliance monitoring for the specific PFAS for which treatment has been installed shall be conducted at least annually. Performance monitoring shall be conducted at least quarterly for the specific PFAS for which treatment has been installed.

(vii) *Waivers.* Systems conducting monitoring under subparagraph (ii) at groundwater or GUDI entry points may apply for a use waiver for those entry points which have 3 consecutive years of quarterly or annual samples with no detection of the PFAS monitored under subparagraph (ii). A use waiver from conducting monitoring under subparagraph (ii)(C) may be granted to a public water supplier with groundwater or GUDI entry points based on documentation provided by the public water supplier and a determination by the Department that the requirements in clauses (A) and (B) have been met. Entry points at which treatment has been installed to remove one or more of the PFAS are not eligible for a waiver.

(A) A use waiver may be granted for a specific entry point after evaluating knowledge of previous use, including storage, manufacturing, transport or disposal of one or more PFAS within the wellhead protection area Zones I and II as defined under § 109.1. If a determination by the Department reveals no previous use, a waiver may be granted for the entry point.

(B) Waiver requests and renewals shall be submitted to the Department, on forms provided by the Department, for review and approval prior to the end of the applicable monitoring period. Until the waiver request or renewal is approved, the public water system is responsible for conducting all required monitoring.

(C) If a use waiver is granted by the Department, required monitoring at that entry point is reduced to one sample during the subsequent compliance period. This monitoring shall be conducted during the quarter that previously yielded the highest analytical result, or as specified by the Department, and in the same years as any reduced monitoring granted for VOCs under paragraph (5)(iv)(B) and SOCs under paragraph (6)(iii) as specified by the Department.

(D) A waiver is effective for one compliance period and may be renewed in each subsequent compliance period.

(viii) *Invalidation of PFAS samples.*

(A) The Department may invalidate results of obvious sampling errors.

(B) A sample invalidated under this subparagraph does not count towards meeting the minimum monitoring requirements of this paragraph.

(ix) *Compliance determinations.* Compliance with the PFAS MCLs shall be determined based on the analytical results obtained at each entry point. If one entry point is in violation of an MCL, the system is in violation of the MCL.

(A) For systems monitoring more than once per year, compliance with the MCL is determined by a running annual average of all samples taken at each entry point.

(B) If monitoring is conducted annually or less frequently, the system is out of compliance if the level of a contaminant at any entry point is greater than the MCL. If a confirmation sample is collected as specified in subparagraph (v), compliance is determined using the average of the two sample results.

(C) If any sample result will cause the running annual average to exceed the MCL at any entry point, the system is out of compliance with the MCL immediately.

(D) If a system fails to collect the required number of samples, compliance with the MCL will be based on the total number of samples collected.

(E) If a sample result is less than the MRL, zero will be used to calculate compliance.

§ 109.303. Sampling requirements.

(a) The samples taken to determine a public water system's compliance with MCLs, MRDLs or treatment technique requirements or to determine compliance with monitoring requirements shall be taken at the locations identified in §§ 109.301, 109.302, 109.1003, 109.1103, 109.1202 and 109.1303 and as follows:

* * * * *

(4) Samples for determining compliance with MCLs for organic contaminants listed by the EPA under 40 CFR 141.61 (relating to maximum contaminant levels for organic contaminants), inorganic contaminants listed by the EPA under 40 CFR 141.62 (relating to maximum contaminant levels for inorganic contaminants), and radionuclide contaminants listed by the EPA under 40 CFR 141.66 (relating to maximum contaminant levels for radionuclides) shall be taken at each entry point to the distribution system which is representative of each source after an application of treatment during periods of normal operating conditions. If a system draws water from more than one source and the sources are combined prior to distribution, the system shall sample at the entry point during periods of normal operating conditions when water is representative of all sources being used.

(5) Asbestos sampling points shall be at the distribution tap where asbestos contamination is expected to be the greatest based on the presence of asbestos cement pipe and lack of optimum corrosion control treatment, and at the entry point for each source which the Department has reason to believe may contain asbestos, except that a collected distribution sample which is representative of a source may be substituted for a required entry point sample.

(6) Samples for determining compliance with MCLs for PFAS contaminants listed in § 109.202(a)(4) shall be collected at each entry point to the distribution system which is representative of each source after an application of treatment during periods of normal operating conditions. If a system draws water from more than one source and the sources are combined prior to distribution, the system shall sample at the entry point during periods of normal operating conditions when water is representative of all sources being used.

(b) The samples taken to determine a public water system's compliance with treatment technique and performance monitoring requirements shall be taken at a point that is as close as practicable to each treatment technique process and that is not influenced by subsequent treatment processes or appurtenances.

* * * * *

§ 109.304. Analytical requirements.

(a) Sampling and analysis shall be performed in accordance with analytical techniques adopted by the EPA under the Federal act or methods approved by the Department.

* * * * *

(e) A water supplier shall calibrate all turbidimeters used for compliance monitoring using the procedure specified by the manufacturer. At a minimum, calibration with an EPA-approved primary standard shall be conducted at least every 90 days. The Department may extend this 90-day calibration frequency if the calibration due date coincides with a holiday or weekend, or during a water system emergency which prevents timely calibration.

(f) For the purpose of determining compliance with the PFAS MCLs established in § 109.202(a)(4) (relating to State MCLs, MRDLs and treatment technique requirements), sampling and analysis for PFAS shall be conducted as follows:

(1) Sampling and analysis shall be according to the following approved methods and MRLs:

Contaminant	*Methods*	*MRL (ng/L)*
(i) PFOA	EPA 533, EPA 537.1, EPA 537 Version 1.1	5
(ii) PFOS	EPA 533, EPA 537.1, EPA 537 Version 1.1	5

(2) Analysis shall be conducted by a laboratory accredited by the Department.

(3) Accredited laboratories must determine the MDL for each analyte, according to the procedure in Appendix B, Revision 2 to 40 CFR Part 136 (relating to definition and procedure for the determination of the method detection limit) or as specified in the method.

(4) Accredited laboratories must analyze Performance Evaluation Samples provided by a third party at least once per year by each method for which the laboratory maintains certification. Results of Performance Evaluation Samples must be within ±30% of the true value.

(5) The MRL must be contained within the range of calibration.

Subchapter D. PUBLIC NOTIFICATION

§ 109.411. Content of a public notice.

(a) *Elements of a public notice.* When a public water system is required to give public notice under this subchapter, each public notice must include the following elements:

* * * * *

(e) *Standard language for a public notice.* Public water systems shall include the following standard language in their public notice:

(1) *Standard health effects language for primary MCL or MRDL violations, treatment technique violations and violations of the condition of a variance or exemption.* Public water systems shall include in each public notice appropriate health effects language. This subchapter incorporates by reference the health effects language specified in 40 CFR Part 141, Subpart Q, Appendix B (relating to standard health effects language for public notification), corresponding to each primary MCL, MRDL and treatment technique violation listed in 40 CFR Part 141, Subpart Q, Appendix A (relating to NPDWR violations and other situations requiring public notice), and for each violation of a condition of a variance or exemption, unless other health effects language is established by regulations or order of the Department.

(i) The health effects language for fluoride is not incorporated by reference. Public water systems shall include the following health effects language in each Tier 2 public notice for violation of the primary MCL of 2 mg/L for fluoride:

"This is an alert about your drinking water and a cosmetic dental problem that might affect children under nine years of age. At low levels, fluoride can help prevent cavities, but children drinking water containing more than 2 milligrams per liter (mg/L) of fluoride may develop cosmetic discoloration of their permanent teeth (dental fluorosis). Dental fluorosis, in its moderate or severe forms, may result in a brown staining and or pitting of the permanent teeth. This problem occurs only in developing teeth, before they erupt from the gums. Drinking water containing more than 4 mg/L of fluoride (the U.S. Environmental Protection Agency's drinking water standard) can increase your risk of developing bone disease."

(ii) Public water systems shall include the following health effects language in each Tier 2 public notice for violation of the primary MCL for PFOA:

"Drinking water containing PFOA in excess of the MCL of 14 ng/L may cause adverse health effects, including developmental effects (neurobehavioral and skeletal effects)."

(iii) Public water systems shall include the following health effects language in each Tier 2 public notice for violation of the primary MCL for PFOS:

"Drinking water containing PFOS in excess of the MCL of 18 ng/L may cause adverse health effects, including decreased immune response."

(2) *Standard language for violations of monitoring requirements.* Public water systems shall include the following language in their notice, including the language necessary to fill in the blanks, for all violations of monitoring requirements listed in 40 CFR Part 141, Subpart Q, Appendix A:

* * * * *

§ 109.416. CCR requirements.

This section applies only to community water systems and establishes the minimum requirements for the content of the annual CCR that each system shall deliver to its customers. This report must contain information on the quality of the water delivered by the system and characterize the risks, if any, from exposure to contaminants detected in the drinking water in an accurate and understandable manner.

* * * * *

(3) Except as noted in subparagraphs (i)—(v), the annual report that a community water system provides to its customers shall contain all of the information, mandatory language and optional text specified by the EPA under 40 CFR 141.153 and 141.154 (relating to content of the reports; and required additional health information), which are incorporated by reference, and under 40 CFR 141, Subpart O, Appendix A (relating to regulated contaminants), which is incorporated by reference, unless other information, mandatory language or optional text is established by regulations or order of the Department. The health effects language for fluoride is not incorporated by reference. Public water systems shall include the health effects language specified in § 109.411(e)(1)(i) (relating to content of a public notice) for violation of the primary MCL of 2 mg/L fluoride.

(i) If a water system wants to use wording of its own choice in place of optional text, the water supplier shall submit the proposed wording to the Department for review and written approval prior to including it in its annual CCR. Once approved, the water supplier's wording may be used in future CCRs without further approval from the Department as long as it is not changed and is still applicable.

(ii) The CCR shall contain information in Spanish regarding the importance of the report or contain a telephone number or address where persons served may contact the water system to obtain a translated copy of the report or to request assistance.

(iii) For each non-English-speaking group other than Spanish-speaking that exceeds 10% of the residents for systems serving at least 1,000 people or 100 residents for systems serving less than 1,000 people, and speaks the same language other than English, the report shall contain information in the appropriate languages regarding the importance of the report or contain a telephone number or address where persons served may contact the water system to obtain a translated copy of the report or to request assistance in the appropriate language. The Department will make the final determination of which systems need to include this information.

(iv) For the purpose of defining how certain portions of a CCR shall appear, the term "prominently display" as used in 40 CFR 141.154(a) means that the information shall be printed either in a larger size typeface or bolded or enclosed within a border or all these so as to make the information conspicuous in comparison to the rest of the text appearing before and after the prominently displayed text. Prominently displayed text placed away from other text (such as, in a highlighted or boxed area) shall be printed no smaller than the text used elsewhere in the body of the report, excluding main or section titles.

(v) Information contained in a CCR shall appear in an easy-to-read format. Font sizes below 10 points or color combinations, or both, that make it difficult for persons to read and understand the information contained in the CCR may not be used.

(3.1) Public water suppliers required to conduct monitoring for PFAS under § 109.301(16) (relating to monitoring requirements) shall also include at a minimum the following information:

(i) Information on results detected.

(A) MCL in ng/L.

(B) MCLG in ng/L.

(C) Highest level detected in ng/L.

(D) Range of detections in ng/L.

(E) Sample dates.

(F) Whether a violation occurred.

(G) *Sources of contamination.* The likely sources of detected contaminants to the best of the public water supplier's knowledge. Specific information regarding contaminants may be available in sanitary surveys or source water assessments and should be used when available. If the public water supplier lacks specific information on the likely source or sources of the contaminant or contaminants, the following statement shall be used:

"Discharge from manufacturing facilities and runoff from land use activities."

(ii) *Health effects language.* Public water systems shall include the health effects language specified in § 109.411(e)(1)(ii) and (iii) for violation of a primary MCL for PFAS specified in § 109.202(a) (relating to State MCLs, MRDLs and treatment technique requirements).

(4) Each community water system shall do the following:

(i) Mail or otherwise directly deliver to each customer one copy of the annual CCR no later than the date specified in paragraph (2).

(ii) Mail a paper copy of the annual CCR to the Department no later than the date the water system is required to distribute the CCR to its customers.

* * * * *

Subchapter E. PERMIT REQUIREMENTS

§ 109.503. Public water system construction permits.

(a) *Permit application requirements.* An application for a public water system construction permit shall be submitted in writing on forms provided by the Department and shall be accompanied by plans, specifications, engineer's report, water quality analyses and other data, information or documentation reasonably necessary to enable the Department to determine compliance with the act and this chapter. The Department will make available to the applicant the Public Water Supply Manual, available from the Bureau of Safe Drinking Water, Post Office Box 8467, Harrisburg, Pennsylvania 17105 which contains acceptable design standards and technical guidance. Water quality analyses shall be conducted by a laboratory accredited under this chapter.

(1) *General requirements.* An application must include:

* * * * *

(iii) *Information describing new sources.* Information describing new sources must include the items specified in clauses (A)—(F). The information specified in clauses (C) and (D) may not be more than 2 years old from the date the permit application is submitted unless the Department approves the use of data more than 2 years old. The Department may accept approval of an out-of-State source by the agency having jurisdiction over drinking water in that state if the supplier submits adequate proof of the approval and the agency's standards are at least as stringent as this chapter:

* * * * *

(D) An evaluation of the quality of the raw water from each new source. For groundwater sources, the evaluation shall be conducted at the conclusion of the constant rate aquifer test. This clause does not apply when the new source is finished water obtained from an existing permitted community water system unless the Department provides written notice that an evaluation is required. The evaluation must include analysis of all of the following:

* * * * *

(XIV) For groundwater sources, the monitoring specified in § 109.302(f) (relating to special monitoring requirements) if the Department determines that the source is susceptible to surface water influence.

(XIV.1) PFAS for which MCLs have been established under § 109.202(a) (relating to State MCLs, MRDLs and treatment technique requirements).

(XV) Other contaminants that the Department determines necessary to evaluate the potability of the source.

* * * * *

Subchapter F. DESIGN AND CONSTRUCTION STANDARDS

§ 109.602. Acceptable design.

(a) A public water system shall be designed to provide an adequate and reliable quantity and quality of water to the public. The design must ensure that the system will, upon completion, be capable of providing water that complies with the primary and secondary MCLs, MRDLs and treatment techniques established in Subchapters B, K, L and M except as further provided in this section.

* * * * *

(i) Alarm and shutdown capabilities must conform to all of the following:

* * * * *

(3) Be capable of notifying the available operator on duty of events triggering an alarm or plant shutdown.

(j) *PFAS.*

(1) The Department identifies the following treatment technologies as acceptable for achieving compliance with the MCLs for PFAS, established under § 109.202(a) (relating to State MCLs, MRDLs and treatment technique requirements):

(i) GAC.

(ii) Ion exchange.

(iii) Reverse Osmosis.

(2) Other treatment technologies may be approved by the Department if the applicant demonstrates the alternate technology is capable of providing an adequate and reliable quantity and quality of water to the public.

Subchapter G. SYSTEM MANAGEMENT RESPONSIBILITIES

§ 109.701. Reporting and recordkeeping.

(a) *Reporting requirements for public water systems.* Public water systems shall comply with the following requirements:

* * * * *

(3) *One-hour reporting requirements.* A public water supplier shall report the circumstances to the Department within 1 hour of discovery for the following violations or situations:

(i) A primary MCL or an MRDL has been exceeded or a treatment technique requirement has been violated under Subchapter B, K, L or M.

(ii) A sample result requires the collection of check or confirmation samples under § 109.301.

(iii) Circumstances exist which may adversely affect the quality or quantity of drinking water including, but not limited to:

* * * * *

Subchapter J. BOTTLED WATER AND VENDED WATER SYSTEMS, RETAIL WATER FACILITIES AND BULK WATER HAULING SYSTEMS

§ 109.1003. Monitoring requirements.

(a) *General monitoring requirements.* Bottled water and vended water systems, retail water facilities and bulk water hauling systems shall monitor for compliance with the MCLs, MRDLs and treatment techniques as follows, except that systems which have installed treatment to comply with a primary MCL shall conduct quarterly operational monitoring for the contaminant which the treatment is designed to remove:

(1) Bottled water systems, retail water facilities and bulk water hauling systems, for each entry point shall:

* * * * *

(xiv) Beginning April 28, 2018, a system that uses or obtains finished water from another permitted public water system using surface water or GUDI sources shall comply with the following requirements:

* * * * *

(C) When the requirements of clause (A) or (B) cannot be achieved, the supplier shall initiate an investigation under the Department's direction to determine the cause, potential health risks and appropriate remedial measures.

(xv) Beginning January 1, 2024, monitor for compliance with the MCLs for PFAS established under § 109.202(a).

(A) *Monitoring exemption.* Systems that obtain finished water from another permitted public water system are exempt from conducting monitoring for PFAS if the public water system supplying the finished water performs the required monitoring at least annually and a copy of the analytical reports are received by the Department.

(B) *Initial monitoring.* Initial monitoring shall consist of 4 consecutive quarterly samples at each entry point. Systems that add new sources to new or existing entry points on or after January 1, 2024, shall conduct initial monitoring according to this clause. An entry point with one or more new sources shall be monitored for 4 consecutive quarters, beginning the first full quarter the entry point begins serving the public.

(C) *Repeat monitoring.* Repeat monitoring for entry points shall be conducted as follows:

(I) For an entry point at which a PFAS is detected during initial monitoring or where a PFAS is detected anytime at a level in excess of its MCL, compliance monitoring for the detected PFAS shall be conducted quarterly. After analyses of four consecutive quarterly samples at an entry point, including initial quarterly monitoring samples, demonstrate that the PFAS level in each quarterly sample is reliably and consistently below the MCL, the required compliance monitoring is reduced to one sample per year at that entry point for the detected PFAS.

(II) For an entry point at which a PFAS is not detected during the initial and subsequent repeat monitoring, repeat monitoring shall be one sample per year from that entry point.

(D) *Confirmation samples.* A confirmation sample shall be collected and analyzed for each of the PFAS detected in exceedance of its MCL during annual monitoring. The confirmation sample shall be collected within 2 weeks of notification from the accredited laboratory performing the analysis of the MCL exceedance.

(E) *Repeat and performance monitoring for entry points with PFAS removal treatment.* Compliance monitoring shall be conducted annually at entry points with PFAS treatment. Performance monitoring shall be conducted at least quarterly for the specific PFAS for which treatment is provided.

(F) *Invalidation of PFAS samples.*

(I) The Department may invalidate results of obvious sampling errors.

(II) A sample invalidated under this clause does not count towards meeting the minimum monitoring requirements of this subparagraph.

(G) *Compliance determinations.* Compliance with the PFAS MCLs shall be determined based on the analytical results obtained at each entry point. If one entry point is in violation of an MCL, the system is in violation of the MCL.

(I) For systems monitoring more than once per year, compliance with the MCL is determined by a running annual average of all samples taken at each entry point.

(II) If monitoring is conducted annually, the system is out of compliance if the level of a contaminant at any entry point is greater than the MCL. If a confirmation sample is collected as specified in clause (D), compliance is determined using the average of the two sample results.

(III) If any sample result will cause the running annual average to exceed the MCL at any entry point, the system is out of compliance with the MCL immediately.

(IV) If a system fails to collect the required number of samples, compliance with the MCL will be based on the total number of samples collected.

(V) If a sample result is less than the MRL, zero will be used to calculate compliance.

(2) Vended water systems shall monitor in accordance with paragraph (1) except that vended water systems qualifying for permit by rule under § 109.1005(b), for each entry point shall:

* * * * *

(b) *Sampling requirements.*

* * * * *

(3) Sampling and analysis shall be performed in accordance with analytical techniques adopted by the EPA under the Federal act or methods approved by the Department in accordance with § 109.304.

(4) Compliance monitoring samples for VOCs, as required under subsection (a)(1)(iii), shall be collected by a person properly trained by a laboratory certified by the Department to conduct VOC or vinyl chloride analysis.

(6) [Reserved].

(c) *Repeat monitoring for microbiological contaminants.*

* * * * *

Subchapter N. DRINKING WATER FEES

§ 109.1403. Monitoring waiver fees.

(a) *New waivers.* An application for a new waiver from the monitoring requirements in §§ 109.301 and 109.302 (relating to general monitoring requirements; and special monitoring requirements) for a single source must be accompanied by a fee as follows:

Waiver Type	*New Waiver Fee*
VOC use waiver	$100
SOC use waiver	$100
SOC susceptibility waiver	$300
IOC waiver	$100
PFAS use waiver	$100

(b) *Waiver renewals.* An application for a waiver renewal from the monitoring requirements in §§ 109.301 and 109.302 for a single source must be accompanied by the appropriate fee as follows:

* * * * *

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Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

STATE BOARD OF VEHICLE MANUFACTURERS, DEALERS AND SALESPERSONS

[49 PA. CODE CH. 19]

Fee Increase

The State Board of Vehicle Manufacturers, Dealers and Salespersons (Board) and the Commissioner of the Bureau of Professional and Occupational Affairs (Commissioner) amend § 19.4 (relating to fees) to read as set forth in Annex A.

Effective Date

This final-form rulemaking will be effective upon publication in the *Pennsylvania Bulletin*. The increased biennial renewal fees will be implemented beginning with the June 1, 2023—May 31, 2025, biennial renewal period. Thereafter, the subsequent graduated increase will be implemented with the biennial renewal for June 1, 2025—May 31, 2027. The graduated increase in initial licensure application fees will be implemented on July 1, 2023, and again on July 1, 2025.

Statutory Authority

Under section 302(a)(9) of the Board of Vehicles Act (act) (63 P.S. § 818.302(a)(9)), the Board is authorized to adopt, promulgate and enforce these rules and regulations consistent with the act as are deemed necessary and proper to effectuate the provisions of the act. Section 304 of the act (63 P.S. § 818.304) requires license holders to pay a biennial renewal fee. Section 321(c) of the act (63 P.S. § 818.321(c)) requires applications for licensure to be accompanied by the required fee. Under section 330(a) of the act (63 P.S. § 818.330(a)), all fees shall be fixed by the Board by regulation and shall be subject to review in accordance with the Regulatory Review Act (71 P.S. § 745.1—745.14). Section 330(a) further requires the Board to increase fees when revenues generated by fees, fines and civil penalties are insufficient to match expenditures over a 2-year period.

Background and Need for the Amendments

This final-form rulemaking increases application fees to reflect updated costs of processing applications and increases all of the Board's biennial renewal fees to ensure its revenue meets or exceeds the Board's current and projected expenses. Section 330(a) of the act requires the Board to increase fees if the revenues generated by fees, fines and civil penalties imposed are not sufficient to meet the expenditures over a 2-year period. The Board raises approximately 93% of its revenue through initial application and renewal fees. The remaining 7% of its revenue comes from other fees, fines and civil penalties. The Board last increased its initial application fees in 2000 and license renewal fees in 2007.

When the Board decided that a fee increase was necessary, the Department of State's Bureau of Finance and Operations (BFO) reported the Board's income and expenses since fiscal year (FY) 2017-2018. In FY 2017-2018, the Board incurred $2,963,270.71 in expenditures and generated only $947,667.84 in revenue, with a remaining balance of $1,130,724.10. In FY 2018-2019, the Board incurred $3,079,102.63 in expenditures and generated $4,584,031.19 in revenue, with a remaining balance of $2,635,652.66. In FY 2019-2020, the Board anticipated expenditures of $3,031,000 and generated $932,000 in revenue, with a remaining balance of $536,652.66. In FY 2020-2021, the Board anticipated expenditures of $3,171,000 and generated $4,007,000 in revenue, with a remaining balance of $1,372,652.66. In FY 2021-2022, the Board was projected to incur $3,122,000 in expenditures and generate $932,000 in revenue, with a deficit balance of ($817,347.34) at the end of FY 2021-2022. In FY 2022-2023, without a fee increase, the Board was projected to incur $3,266,000 in expenditures and generate $4,007,000 in revenue, resulting in a remaining balance of ($76,347.34). Finally, in FY 2023-2024, the Board is projected to incur $3,216,000 in expenditures and generate $932,000 in revenue, with a deficit balance of ($2,360,347.34) at the end of FY 2023-2024. Thus, the BFO's data demonstrated that the Board's revenue is not sufficient to meet or exceed its expenditures over a 2-year period. The BFO recommended, and the Board agreed, to amend a total of 16 fees, consisting of eight initial application fees and eight biennial renewal fees on a graduated basis.

The Board released an exposure draft of a proposed annex reflecting fee increases for public comment from stakeholders, interested parties and representatives of the licensed professions on August 6, 2020. Thereafter, notice of the proposed rulemaking was published at 51 Pa.B. 3230 (June 12, 2021) for review and comment. Publication was followed by a 30-day public comment period during which the Board received no public comments. In addition, the House Professional Licensure Committee (HPLC) and Senate Consumer Protection/Professional Licensure Committee (SCP/PLC) did not submit comments. The Independent Regulatory Review Commission (IRRC) submitted comments as detailed as follows.

Summary of Comments and the Board and Commissioner's Response

Reasonableness of fee increases

First, IRRC asked the Board to explain why increasing the initial application and renewal fees are reasonable. Regarding application fees, initial application fees for salespersons, manufacturer representatives or distributor representatives, manufacturers, manufacturer or distributor branches, distributors, dealers, auctions, and dealer branch lots were last increased in 2000. The Board, with the encouragement and support of the Bureau of Professional and Occupational Affairs (Bureau), determined that a re-evaluation of all application fees for all boards and commissions was appropriate. The Board evaluated all of its application fees and found that fees currently charged did not cover the costs to process applications. Boards and commissions under the Bureau determine initial application fees by calculating the cost to process applications. This approach is fair and reasonable because existing licensees, who pay biennial renewal fees, should not be burdened with financing the cost to process individual applications. As a part of the fee increase recommendations, the BFO recommended graduated application and biennial renewal fee increases so that the application fee increases are more reflective of actual costs to process applications and coincide more closely with the projected expenses for each biennium. The Board adopts the graduated fee schedule in an effort to minimize the impact of fee increases to licensees and to ensure that fee increases only occur when it is fiscally necessary to do so.

When calculating application fees, boards rely on time study reports created within the Bureau that lay out each step in processing an application and the amount of time it takes to complete each step. That amount of time per application is multiplied by the total number of anticipated application requests for 1 year to get the total number of minutes per year necessary to process applications. (The number of minutes per year is multiplied by two since the increases are biennial.) Application fees are based on a formula that multiplies the number of minutes to perform the processing function by the pay rate for the classification of the personnel performing the function and adding a proportionate share of administrative overhead. As reflected in the fee report forms, Board counsel has a significant role in the initial application process. Applications that contain a criminal conviction history must be reviewed and approved by Board counsel. Depending on the applicant's criminal conviction, Board counsel may have to perform additional functions as part of the application process.

The Board and the Commissioner submit that the graduated application fee increases are appropriate and reasonable because the increased fees are projected to cover the cost to process the applications for that biennial period. The Board carefully considered the best way to implement an increase in application fees and determined that a graduated fee schedule is favorable because it aligns the actual cost to process applications in each biennial period with the fee for that period. While the Board is reluctant to put additional fiscal burdens on its licensees and applicants, the increased fees are not significant when looking at the total increase in dollars. Moreover, even with the implementation of the graduated fee increase, the Board's fees are still comparable with other states. The Board and the Commissioner do not believe the increases will deter applicants from applying for licensure in this Commonwealth or put this Commonwealth at a competitive disadvantage. Biennial renewal fees were last increased in 2007. Biennial renewal fees go towards the costs of operating the board, which includes the Bureau, Commissioner and Revenue office costs, departmental services, board member expenses, legal office costs, hearing expenses and costs relating to enforcement and investigations. While the Board is cognizant of the desire of licensees to keep licensure fees low, the Board must balance that desire with the need to generate sufficient revenue to ensure the fiscal integrity of the Board and to assure that the Board is fiscally able to carry out its duties under the act.

Comparison to other States shows that fee increases are reasonable

In comparing the Board's fees to other states, of the states in the Northeastern Region (Connecticut, Delaware, Maine, New Hampshire, New Jersey, New York, Rhode Island, Ohio, Massachusetts, Pennsylvania, Maryland and West Virginia), only Ohio, Maryland and West Virginia require licensure for salespersons, with applications fees of $10, $67.50 and $32—$60 ($25 examination fee plus $7 fee for every year to be licensed, up to 5 years), respectively. Maryland requires renewal every 3 years at $202.50, Ohio requires annual renewal at a cost of $10 and West Virginia licenses renew every 5 years at a cost of $10. The states that require initial licensure applications for salespersons charge fees ranging from $10 to $67.50. Pennsylvania currently charges a fee of $25 for a new salesperson application, with the proposed increase raising that fee to $65 effective July 1, 2023, and to $70 effective July 1, 2025. Only Ohio ($10) will have an initial salesperson license application fee lower than Pennsylvania. The states that charge salesperson license renewal fees range from $10 to $202.50. In addition, Pennsylvania currently charges a fee of $90 for a salesperson license renewal application, with the proposed increase raising that fee to $113 effective June 1, 2023, and to $141 effective June 1, 2025. Only Ohio ($10 annually) and West Virginia ($10) will have license renewal fees lower than Pennsylvania. However, based upon the Board's experience in the vehicle profession, it does not believe that the $10 to $60 difference in initial salesperson application fees and the $61.50 difference in salesperson renewal application fees will deter salesperson applicants or licensees from obtaining and renewing licenses.

When considering this proposed fee increase, the Board conducted a comparison of application fees and renewal fees charged by surrounding states. The Board found that even by comparing the highest fee increases, the Commonwealth's application fees and renewal fees are still in line with fees charged in surrounding states. The application and renewal fees for dealers vary widely. The license application fees for dealers are: Connecticut $140, Delaware $100, Maine $150, Maryland $225, New Hampshire $250, New Jersey $257.50, New York $487.50, Massachusetts is set by each municipality, Ohio $254.75, Rhode Island $302.50, West Virginia $250 and Vermont $503. Not all of the states requiring licensure require renewal. The following states renew biennially: Connecticut (new car dealer $700; used car dealer $560), Maryland ($225), New York ($487.50) and Ohio ($254.75). The following states renew annually: New Hampshire ($400 + based upon number of dealer plates), New Jersey ($100), West Virginia ($250) and Vermont ($503). Connecticut, Maine and Pennsylvania are the only states that license dealer branch lots, with Connecticut and Maine charging $100. Pennsylvania currently charges a fee of $65 for new dealer and dealer branch lot applications, with the proposed increase raising those fees to $175 effective July 1,

2023, and to $190 effective July 1, 2025. Additionally, Pennsylvania currently charges a fee of $175 for a biennial renewal for dealers and dealer branch lots, with the proposed increase raising those fees to $219 effective June 1, 2023, and to $274 effective June 1, 2025. The states that require initial licensure applications for dealers charge fees ranging from $100 to $503. Connecticut ($140), Delaware ($100) and Maine ($150) will have initial license application fees lower than Pennsylvania. The states that charge license renewal fees range from $100 to $700. Connecticut ($100) and Maine ($150) will have license renewal fees lower than Pennsylvania. However, based upon the Board's experience in the vehicle profession, it does not believe that the $40 to $90 difference in dealer initial application fees and $124 difference in renewal application fees will deter dealer applicants or licensees from obtaining and renewing licenses.

Connecticut, Delaware, Maine, Maryland, Ohio, New Jersey, Rhode Island and West Virginia require licensure of manufacturers. Manufacturers in those states charge initial licensure fees of $2,300; $75; $1,500; $180—$1,800 (depending on the number of cars made); $100; $257.50; $302.50 and $250, respectively. Of the previous states, only Connecticut, Delaware, Maryland and Rhode Island charge a biennial renewal of $2,300; $100; $180—$1,800 (depending on the number of cars made); and $302.50; respectively. Pennsylvania currently charges a fee of $30 for a manufacturer application, with the proposed increase raising those fees to $90 effective July 1, 2023, and to $100 effective July 1, 2025. Pennsylvania currently charges a fee of $250 for a biennial renewal for a manufacturer, with the proposed increase raising those fees to $313 effective June 1, 2023, and to $391 effective June 1, 2025. Additionally, of the states that license manufacturers, only Maryland and Pennsylvania charge a fee to license manufacturer branches; Maryland's manufacturer branch application fee is $1,800. Pennsylvania currently charges a fee of $30 for a manufacturer branch application, with the proposed increase raising those fees to $90 effective July 1, 2023, and to $100 effective July 1, 2025. For biennial renewal, Pennsylvania currently charges a fee of $175 for a manufacturer branch, with the proposed increase raising those fees to $219 effective June 1, 2023, and to $274 effective June 1, 2025. The states that require initial licensure applications for manufacturers charge fees ranging from $75 to $2,300. Only Delaware ($75) will have an initial license application fee lower than Pennsylvania. Delaware ($100) and Rhode Island ($302.50) are the only states that charge a manufacturer renewal fees that will be lower than Pennsylvania. Based upon the Board's experience in the vehicle profession, it does not believe that a $25 difference in initial fees and $88.50 to $291 in manufacturer renewal fees will deter manufacturer applicants or licensees from obtaining and renewing licenses.

Ohio, Connecticut, Delaware, Massachusetts and Rhode Island require licensure of manufacturer representatives; in Massachusetts, manufacturer representatives are licensed at the municipal level. The application fee in Ohio is $154.75; in Connecticut and Delaware, manufacturer representatives are licensed by the Department of Revenue annually at $100 and $75, respectively; and in Rhode Island, the application fee is $102.50 and annually renews at a fee of $102.50. Pennsylvania currently charges a fee of $25 for a new manufacturer representative application, with the proposed increase raising that fee to $65 effective July 1, 2023, and to $70 effective July 1, 2025. Additionally, Pennsylvania currently charges a fee of $90 for a biennial renewal for a manufacturer representative, with the proposed increase raising that fee to $113 effective June 1, 2023, and to $141 effective June 1, 2025. The states that require initial licensure applications for manufacturer representatives charge fees ranging from $75 to $154.75, all of which remain higher than the proposed fee for Pennsylvania. The only state that charges a manufacturer representative license renewal fee is Rhode Island ($102.50). Based upon the Board's experience in the vehicle profession, it does not believe that an increase in manufacturer representative initial application fees and the $38.50 difference in vehicle manufacturer representative renewal application fees will deter manufacturer representative applicants or licensees from obtaining and renewing licenses.

Maine, Ohio, New York and West Virginia are the only states licensing or requiring a permit for auctions. The fee in Maine is $150 annually. Ohio auction fees range from $100 for auctions to $7,500 for construction equipment auctions. New York auction fees range from $100—$500. The West Virginia auction fee is $250. Pennsylvania currently charges a fee of $65 for a new auction application, with the proposed increase raising that fee to $175 effective July 1, 2023, and to $190 effective July 1, 2025. Of the previously listed states that license auctions, Ohio and West Virginia charge a biennial renewal fee of $10. Pennsylvania currently charges an initial application fee of $65, with the proposed increase raising that fee to $175 effective July 1, 2023, and to $190 effective July 1, 2025. Additionally, Pennsylvania currently charges a renewal fee of $175 for an auction, with the proposed increase raising that fee to $219 effective June 1, 2023, and to $274 effective June 1, 2025. The states that require initial licensure applications for auctions charge fees ranging from $100 to $7,500. Only Ohio ($100 for auctions) will have an initial auction license application fee lower than Pennsylvania. Ohio ($10) and West Virginia ($10) are the only states that charge auction renewal fees that will be lower than Pennsylvania. Based upon the Board's experience in the vehicle profession, it does not believe that the $90 difference in auction initial application fees and $274 in auction renewal application fees will deter auction applicants or licensees from obtaining and renewing licenses.

Delaware, Maine, Maryland and Ohio currently license distributors, with an initial licensure fee for Delaware of $100 per year (with an additional $75 for a wholesale license); Maine charging $1,500; Maryland fees ranging from $180—$1,800 (depending on the number of cars sold); and Ohio charging $154.75. Of the previous, only Delaware and Maryland charge a biennial renewal fee of $100 and $450, respectively. Pennsylvania currently charges a fee of $30 for a new distributor or distributor branch application, with the proposed increase raising those initial application fees to $90 effective July 1, 2023, and to $100 effective July 1, 2025. Additionally, Pennsylvania currently charges a fee of $175 for a biennial renewal for a distributor, with the proposed increase raising that fee to $219 effective June 1, 2023, and to $274 effective June 1, 2025. The states that require initial licensure applications for distributors charge fees ranging from $100 to $1,800. A state that charges a fee will not have initial distributor license application fees lower than Pennsylvania. Delaware ($100) is the only state that charges a distributor renewal fee that will be lower than Pennsylvania. Based upon the Board's experience in the vehicle profession, it does not believe that a distributor initial application fee increase and the $174

difference in distributor renewal fees will deter distributor applicants or licensees from obtaining and renewing licenses.

Controlling expenses

IRRC asked the Board what steps have been taken to control expenses. The BFO meets with the Board annually to review its budget for the prior fiscal year and to suggest any measures they see that may assist the Board with minimizing costs. One area in which the Board has lowered its costs from previous years has been to limit the amount of travel that Board members take to various association meetings, both in-State and out-of-State, instead encouraging attendance virtually. The Board has also converted its meetings to a hybrid format, wherein Board members are permitted to attend either in-person or virtually. This has allowed the Board to decrease expenses related to hotel and mileage reimbursement for those Board members that choose to attend virtually.

The majority of the Board's operational costs are personnel-related, and much of those costs are not within the Board's control. Staff are generally employees of the Commonwealth, most of whom are civil service personnel; many are in union positions. For these employees, the Board is bound by the negotiated contract. Personnel costs associated with investigation and enforcement depend largely on the number of complaints received that need to be investigated, and the number of those matters that result in disciplinary action. The Board has no control over the number of complaints that are filed against licensees and unlicensed individuals, nor may they control which matters are, or are not, prosecuted. Application fees are calculated to cover the cost of processing applications while the biennial fees are calculated to ensure that the Board can meet or exceed its operational costs.

The Board's fee increase represents the least burdensome alternative.

Next, IRRC asked the Board to explain how the Board's fee increase represents the least burdensome alternative for applicants and existing licensees. As a part of the BFO's fee increase recommendations, the BFO recommended graduated application and biennial renewal fee increases so that the application fee increases are reflective of actual costs to process applications and so that biennial renewal fees coincide more closely with the projected expenses for each biennium. The Board adopts the graduated fee schedule in an effort to minimize the impact of fee increases to licensees and to ensure that fee increases only occur when it is fiscally necessary to do so.

The Board considers this regulation to be the least burdensome and acceptable alternative, consistent with public health, safety and welfare. This increase is necessary to ensure the fiscal integrity of the Board and to assure that the Board's mandate to protect the health, safety and welfare of the public is carried out. The last time that the Board approved an increase in initial application fees was 2000 and biennial renewal fee increase was in 2007.

When the BFO first alerted the Board that fee increases were necessary, the Board was looking at substantial increases in biennial renewal fees only. The Board later decided to incorporate increased fees for application fees to reflect the current costs to process those applications. The Board considered a one-time 20% increase in application and renewal fees and determined that a graduated increase offered the best protection of the Board against the loss of licensees resulting from the natural fluctuations in the industry and provision of resources to the Board for compliance with statutory requirements. However, the Board incorporated graduated fee increases for applications and biennial fees over the course of 2 biennial periods so that the fees for each biennium more accurately reflected the actual costs for each biennial period. The Board adopted what it believed to be the least burdensome acceptable fee structure as this method minimizes the impact of fee increases to licensees and ensures that fee increases only occur when it is fiscally necessary to do so.

Factors that have contributed to the rise in the number of investigations, open cases and disciplinary matters.

Based, in part, on costs for this Board for investigations, legal services and hearings, the Board anticipates that its expenditures will continue to increase because the cost to operate the Board continues to grow due factors outside of the Department's control. Since FY 2011-2012, the Board's revenue has held stagnant, but the expenditures are now outpacing the revenues.

Over the last few fiscal years, the Board has had some sizable increases to expenses for a variety of reasons. One of the largest financial impacts for the Board was the incorporation of The Pennsylvania Justice Network (JNET), due in part to the enactment of the act of February 15, 2018 (P.L. 14, No. 6) (Act 6 of 2018), which requires mandatory self-reporting of criminal convictions. The Board uses JNET to identify criminal convictions of licensees and to verify compliance with Act 6 of 2018's mandatory reporting requirement. Initially, the Board was one of three boards under the Bureau that incorporated JNET criminal notifications into their business processes. Across the three boards, there was a sizable 27.5% average increase in the number of complaints being processed and opened for prosecution. With the additional complaints, increased expenses due to higher prosecutions, investigations, expert witness usage and hearings resulted. Since incorporation of JNET, expenses have been relatively steady in all of these cost categories. More than likely, this new level of legal workload is one that will be part of the financial picture for the Board going forward, as the JNET reports that are submitted to the Board show no signs of slowing. The public is also permitted to submit complaints electronically by means of the Pennsylvania Licensing System (PALS) web site, which is a function that was not available in the past.

IRRC also asked the Board if the open investigations, open cases and sanctions resulted in a substantial increase in fines and civil penalties. While the Board has the ability to assess fines, civil penalties, and attempts to recoup the cost of investigations, it does not have the ability to enforce that those fees be paid back to the Board, as that is a function limited to the Department of State's prosecution division. If the civil penalty has not been paid after 30 days, the Board may also forward the matter to the Attorney General's office for collection. Investigative costs have remained relatively level over the course of the past few fiscal years, while legal and hearing expenses have certainly increased over time. The fines, civil penalties and investigation recoupment were never designed to fully cover the cost of the work completed, therefore, the funds to complete these activities must be covered by the licensees.

With the incorporation of JNET, the Board is now alerted to any licensee that may be arrested and convicted, whether that license is active or not. In the past, the Board would not be notified of these arrests and convictions until a licensee filed a renewal application or

if a licensee self-reported. As a result, many new files are opened that were not opened prior to JNET. Of those new files, a large portion are closed when the arrest does not result in a conviction. Even when the Board imposes significant fines or civil penalties, the Board is not very successful in collecting those fines or civil penalties. For example, a salesperson is more likely to abandon their license and leave the profession than pay a large fine. Additionally, when the Board turns over a collection to the Office of Attorney General, the Board pays a 25% collection fee. Generally, the boards do not budget in a manner that depends on fines and civil penalties because as a revenue stream they are undependable.

Which newly enacted amendments require increased revenue necessary for the Board to carry out its obligations?

IRRC asked the Board which newly enacted amendments to the act require increased revenue for the Board to carry out its obligations. The act was amended in 2018 to allow the Board to issue temporary permits for new dealers. The Board anticipated an increase in costs due to investigations that may arise for temporary permitholders. Additionally, the act was amended in 2018 to renumber each section as well as separate all sections related to recreational vehicles. The amendments created additional statutory conditions for out-of-State dealers participating in recreational vehicle (RV) shows, including posting of a bond and payment of a participation fee. These new requirements may impact investigative and legal costs due to responding to complaints regarding out-of-State RV dealers' participation and compliance with the act.

Information technology upgrade

In addition to the legal increases, all 29 boards and commissions under the Bureau have undergone an information technology transformation upgrade with the incorporation of PALS. Expenses associated with PALS, including the initial build as well as ongoing maintenance, are proportionately spread across all entities based on licensee population to effectively share costs per licensee. While the initial build is in the past, it has contributed to higher administrative expenses for all boards and commissions during the last few fiscal years. Due to PALS' high functioning database with enhanced features over the Department's previous License 2000 platform, maintenance for this system requires a larger financial commitment from all boards and commissions than the previous system. The Board anticipates that the maintenance costs for the PALS system will decrease from its prior levels as the system becomes more consistent in its functionality.

Other Comments on the Regulatory Analysis Form

IRRC commented that the Board did not attach to the Regulatory Analysis Form (RAF) the fee report forms for the biennial renewal fees. Renewal fees are not calculated on a per cost basis the way initial application fees are calculated. Thus, the Board does not create fee report forms to accompany renewal fee recommendations. Initial application fees are developed at cost fee whereas renewal fees are developed to generate revenue to meet or exceed the Board's expenditures.

IRRC commented that the Board included inconsistent figures for the number of license renewals in questions 16 and 17 of the RAF. This error was caused by one section indicating annual figures and the other biennial figures. The revisions are made to each document. IRRC also asked the Board to update the dates of Board meetings in questions 14 and 30 of the RAF. The Board makes the suggested updates in the RAF.

IRRC asked the Board to include in this final-form rulemaking the actual expenditure figure for FY 2019-2020. The actual expenses for FY 2019-2020 are $2,891,103.52. An updated Annual Board Budget Report is added to the RAF.

Titles of fees

IRRC asked the Board to make certain that titles of fees are consistently used in the preamble, RAF and this final-form rulemaking. To make terms consistent among documents, the Board in the proposed rulemaking chose to revise the term "factory" to "manufacturer" in § 19.4 of the regulation. The Board would note that "factory" is an outdated term that was used interchangeably in the past with the term "manufacturer." The term "factory" is no longer used within the industry and deleting it will allow the Board to update its terminology and provide consistency between the initial application fee section and the renewal fee section of § 19.4 of the regulations. The Board adds the word "lot" to the term "dealer branch license" in the license renewal fees and the word "distributor" to the term "manufacturer branch license" in the annex; the Board drafted this final-form rulemaking consistent with these amendments.

Fiscal Impact

The final amendments will increase the application and biennial renewal fees for all licensees of the Board. Based upon current licensee counts, there are approximately 12 manufacturer or distributor branches; 57 auctions; 373 dealer branch lots; 6,252 dealers; 63 distributors; 296 manufacturers; 1,108 manufacturer or distributor representatives and 28,746 salespersons for a total of approximately 36,907 licensees who will be required to pay more to renew their licenses. Based upon these fee increases, the total economic impact per fiscal year is as follows:

FY 2022-2023:	$1,292,908
FY 2023-2024:	$290,310
FY 2024-2025:	$1,267,670
FY 2025-2026:	$37,035
TOTAL	$2,887,923

These fees may be paid by applicants and licensees, or an employer may elect to pay the application fee of an employee. This final-form rulemaking should have no other fiscal impact on the private sector, the general public or political subdivisions of the Commonwealth.

This final-form rulemaking requires the Board to alter its online initial licensure applications and biennial renewal forms to reflect the new fees; however, the amendments will not create additional paperwork for the regulated community or for the private sector.

Sunset Date

The Board continuously monitors the effectiveness of its regulations. Therefore, no sunset date has been assigned. Additionally, the BFO provides the Board with an annual report detailing the Board's financial condition. In this way, the Board continuously monitors the adequacy of its fee schedule.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on May 26, 2021, the Board submitted a copy of the notice of proposed rulemaking, published at 51 Pa.B. 3230, to IRRC, the HPLC and the SCP/PLC for review and comment.

Under section 5(c) of the Regulatory Review Act, the Board shall submit to IRRC, the HPLC and the SCP/PLC

copies of comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Board has considered all comments from IRRC, the HPLC, the SCP/PLC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on November 30, 2022, the final-form rulemaking was deemed approved by the HPLC and the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on December 8, 2022, and approved the final-form rulemaking.

Additional information

Additional information may be obtained by writing to Janice Cline, Board Administrator, State Board of Vehicle Manufacturers, Dealers and Salespersons, P.O. Box 2649, Harrisburg, PA 17105-2649, RA-ST-VEHICLE@pa.gov.

Findings

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202), referred to as the Commonwealth Documents Law and the regulations promulgated thereunder 1 Pa. Code §§ 7.1 and 7.2 (relating to notice of proposed rulemaking required; and adoption of regulations).

(2) A public comment period was provided as required by law and any comments were considered in drafting this final-form rulemaking.

(3) The amendments to this final-form rulemaking do not enlarge the original purpose for the proposed rulemaking published at 51 Pa.B. 3230.

(4) These amendments to the regulations of the Board are necessary and appropriate for the regulation of the vehicle profession in the Commonwealth.

Order

The Board, acting under its authorizing statute, orders that:

(A) The regulations of the Board at 49 Pa. Code Chapter 19, are amended by amending § 19.4 to read as set forth in Annex A, with ellipses referring to the existing text of the regulation.

(B) The Board shall submit this final-form rulemaking to the Office of the Attorney General and the Office of General Counsel for approval as required by law.

(C) The Board shall submit this final-form rulemaking to IRRC, the HPLC and the SCP/PLC as required by law.

(D) The Board shall certify this final-form rulemaking and shall deposit it with the Legislative Reference Bureau as required by law.

(E) This final-form rulemaking shall take effect immediately upon publication in the *Pennsylvania Bulletin*.

KIRK A. DAVIS,
Chairperson
State Board of Vehicle Manufacturers, Dealers and Salespersons

ARION R. CLAGGETT,
Acting Commissioner
Bureau of Professional and Occupational Affairs

(*Editor's Note*: See 52 Pa.B. 8009 (December 24, 2022) for IRRC's approval order.)

Fiscal Note: Fiscal Note 16A-6015 remains valid for the final adoption of the subject regulation.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 19. STATE BOARD OF VEHICLE MANUFACTURERS, DEALERS AND SALESPERSONS

GENERAL PROVISIONS

§ 19.4. Fees.

The following is the schedule of fees charged by the Board:

		Effective July 1, 2023	*Effective July 1, 2025*
Salesperson license application	$25	$65	$70
Manufacturer representative or distributor representative license application	$25	$65	$70
Manufacturer license application	$30	$90	$100
Manufacturer or distributor branch license application	$30	$90	$100
Distributor license application	$30	$90	$100
Dealer license application	$65	$175	$190
Auction license application	$65	$175	$190
Dealer branch lot license application	$65	$175	$190

* * * * *

		June 1, 2023—May 31, 2025 Biennial Renewal Fee	*June 1, 2025—May 31, 2027 Biennial Renewal Fee and thereafter*
Biennial renewal—salesperson license	$90	$113	$141
Biennial renewal—manufacturer representative or distributor representative license	$90	$113	$141
Biennial renewal—manufacturer license	$250	$313	$391
Biennial renewal—manufacturer or distributor branch license	$175	$219	$274
Biennial renewal—distributor license	$175	$219	$274
Biennial renewal—dealer license	$175	$219	$274
Biennial renewal—auction license	$175	$219	$274
Biennial renewal—dealer branch lot license	$175	$219	$274

[Pa.B. Doc. No. 23-47. Filed for public inspection January 13, 2023, 9:00 a.m.]

Title 55—HUMAN SERVICES

DEPARTMENT OF HUMAN SERVICES

[55 PA. CODE CH. 1101]

Interrelationship of Providers

The Department of Human Services (Department), under the authority of section 403.1(a)(6) of the Human Services Code (code) (62 P.S. § 403.1(a)(6)), amends § 1101.51 (relating to ongoing responsibilities of providers) to read as set forth in Annex A. Notice of the proposed rulemaking was published at 51 Pa.B. 3468 (June 26, 2021).

Purpose of this Final-Form Rulemaking

The purpose of this final-form rulemaking is to delete § 1101.51(c)(3), which prohibits providers from leasing or renting space, shelves or equipment within a provider's office to another provider or from allowing the paid or unpaid staff of a provider to be placed in another provider's office.

Developments in the health care industry have emphasized the need for integrated health care. The Department recognizes the benefits of integrated care and deletes this subsection to support the enrollment in the Medical Assistance (MA) Program of providers that share space (co-locating providers). By expanding provider qualifications to include co-locating providers, the Department seeks to support more coordinated and integrated care within the MA Program.

Background

Section 1407(a)(2) of the code (62 P.S. § 1407(a)(2)) provides that it is unlawful to solicit or receive or to offer or pay any remuneration, including any kickback, bribe or rebate, directly or indirectly, in cash or in kind from or to any person in connection with the furnishing of services or merchandise for which payment may be in whole or in part under the MA Program or in connection with referring an individual to a person for the furnishing or arranging for the furnishing of any services or merchandise for which payment may be made in whole or in part under the MA Program. The Department promulgated the regulation in § 1101.51(c)(3) to provide specific examples of the types of arrangements that section 1407(a)(2) of the code prohibits. Among the examples is that providers may not "lease or rent space, shelves or equipment within a provider's office to another provider or allowing the placement of paid or unpaid staff of another provider in a provider's office."

This regulation prevented co-locating providers from enrolling in the MA Program. Since promulgation of this regulation, the health care industry has moved to a more integrated approach to diagnosis and treatment of conditions or injuries. To support that trend, retail clinics, some of which are placed within the same building as a pharmacy, have emerged, and multidisciplinary providers, including physical and behavioral health providers, have entered into co-location arrangements between distinct providers.

According to an informational bulletin issued by the Centers for Medicare & Medicaid Services on January 16, 2014, titled "Reducing Non-Urgent Use of Emergency Departments and Improving Appropriate Care in Appropriate Settings," increasing access to primary care services, including through urgent care and retail clinics, has been estimated to result in a potential savings of $4.4 billion Nationwide. Mann, C. (January 16, 2014). Reducing Nonurgent Use of Emergency Departments and Improving Appropriate Care in Appropriate Settings. Retrieved from https://www.hhs.gov/guidance/document/reducing-nonurgent-use-emergency-departments-and-improving-appropriate-care-appropriate. These arrangements increase consumer access to services, including behavioral health and substance use disorder services. Co-location can decrease out-of-pocket costs to beneficiaries related to transportation and childcare and encourage follow-up with referred providers. Co-location can encourage contact between providers and foster communication about shared patients. Medicaid and CHIP Payment and Access Commission (March 2016). Report to Congress on Medicaid and CHIP. Retrieved from https://www.macpac.gov/publication/march-2016-report-to-congress-on-medicaid-and-chip/. The Department, by establishing provider qualifications that incorporate co-locating providers, supports these advancements in the health care industry when services are provided in a manner that allows the beneficiary to retain freedom to choose the service provider and is not automatically directed to or referred to a co-located provider.

After reviewing the trend in the health care delivery system toward integrated care, the Department determined that a narrow interpretation of § 1101.51(c)(3) is more restrictive than required to comply with the code and prevents co-locating providers who are otherwise

eligible from enrolling in the MA Program. On May 28, 2016, the Department issued Statement of Policy (SOP) 1101-16-03, codified in § 1101.51a (relating to clarification of the term "within a provider's office"—statement of policy), to clarify the meaning of "within a provider's office" and the guidelines for providers that enter into co-location arrangements with other participating providers. See 46 Pa.B. 2683 (May 28, 2016); 55 Pa. Code § 1101.51a. The Department also developed an attestation form to be utilized by providers seeking to co-locate, in which each provider attests to its compliance with Federal and State antikickback laws, the Health Insurance Portability and Accountability Act of 1996 (Pub.L. No. 104-191) (HIPAA), and MA beneficiary freedom of choice. The Department will rescind the SOP upon the effective date of this final-form rulemaking.

In an effort to establish provider qualifications that allow co-locating providers to enroll in the MA Program, the Department deletes the regulation in § 1101.51(c)(3), which prohibits providers from leasing space within a provider's office to another provider. Allowing different types of providers to be located in the same space benefits MA beneficiaries by providing the opportunity for a more integrated approach to healthcare. Providers must continue to comply with any other applicable law, including HIPAA, Federal and State antikickback and self-referral laws, and the requirement to provide MA beneficiaries with freedom of choice.

The deletion of the regulation in § 1101.51(c)(3) does not invalidate other laws or requirements affecting co-locating providers if, for example, they are prohibited by law, including licensing laws, or certification requirements, from leasing or renting space, shelves or equipment or otherwise sharing space.

Requirements

The following is a summary of the specific provision in this final-form rulemaking:

§ 1101.51(c)(3) (relating to ongoing responsibilities of providers)

The Department deletes subsection (c)(3) to allow co-locating providers to enroll in the MA Program and to support integrated health care in the MA Program. Deletion of subsection (c)(3) allows MA beneficiaries to receive services in a more integrated manner, consistent with developments in the health care industry.

Affected Individuals and Organizations

Nine co-located providers operating at 82 separate locations have requested and received a waiver of the regulation in § 1101.51(c)(3) from the Department Secretary. Under § 1101.51a, beginning May 28, 2016, any provider who enrolled and was co-located with another provider had to complete an attestation. Current waivers and attestations will remain in effect until publication of this final-form rulemaking which eliminates the co-location provision in § 1101.51(c)(3).

The deletion of § 1101.51(c)(3) provides the regulatory framework to promote integrated health care services by establishing provider qualifications that allow providers that co-locate to enroll in the MA Program. Providers that want to co-locate in the future will be able to do so without obtaining a waiver or submitting an attestation.

Accomplishments and Benefits

This final-form rulemaking deletes the regulatory provision that has prevented or delayed enrollment of providers who are co-located. Allowing different types of providers to be located in the same space will benefit MA beneficiaries by providing the opportunity for a more integrated approach to health care.

Fiscal Impact

There is no fiscal impact.

Contact Persons

Interested persons are invited to submit written comments, suggestions or objections regarding this final-form rulemaking to Lacey Gates, Department of Human Services, Office of Medical Assistance Programs, Bureau of Policy, Analysis and Planning, P.O. Box 2675, Harrisburg, PA 17120, RA-PWMAProgComments@pa.gov. Reference regulation # 14-549 in the subject line.

Persons with a disability who require an auxiliary aid or service may use the Pennsylvania Hamilton Relay Service, (800) 654-5984 (TDD users) or (800) 654-5988 (voice users).

Paperwork Requirements

This final-form rulemaking does not require additional reports or paperwork or any new forms. Less paperwork is required because an attestation form is not required for enrollment of providers that are co-located.

Effective Date

This final-form rulemaking will take effect upon publication in the *Pennsylvania Bulletin*.

Public Comment

Written comments, suggestions and objections regarding the proposed rulemaking were requested within a 30-day period following its publication at 51 Pa.B. 3468. The Department received written responses from five commentators. The comments represented feedback from a provider and from associations, including provider associations and advocates. The Independent Regulatory Review Commission (IRRC) advised the Department that it had no objections, comments or recommendations.

The following is a summary of the comments received within the public comment period and the Department's responses to those comments.

Comment: Four commentators offered support of the proposed rulemaking.

Response: The Department acknowledges these comments and thanks the commentators for the support.

Comment: One commentator requested clarification from the Department that none of the proposed changes shall be construed to override the consumer protections contained in Act 122 of 2013, which include prohibiting the placement of laboratory personnel in a provider's office.

Response: The Department acknowledges the concerns with respect to section 3 of the act of December 18, 2013 (P.L. 1232, No. 122), amending The Clinical Laboratory Act (35 P.S. §§ 2151—2165). None of the proposed changes invalidate other laws or requirements affecting providers. If providers are prohibited from co-locating or from leasing or renting space, shelves or equipment by a law, licensing, certification or other requirement, those requirements remain in effect.

Regulatory Review Act

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on June 10, 2021, the Department submitted a copy of the notice of proposed rulemaking, published at 51 Pa.B. 3468, to IRRC and the Chairper-

sons of the House Health Committee and the Senate Health and Human Services Committee for review and comment.

Under section 5(c) of the Regulatory Review Act, the Department is required to submit to IRRC and the House and Senate Committees copies of comments received during the public comment period, as well as other documents when requested. In preparing this final-form rulemaking, the Department has considered all comments from IRRC, the House and Senate Committees, and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on November 30, 2022, the final-form rulemaking was approved by the House and Senate Committees. Under section 5.1(e) of the Regulatory Review Act, IRRC met on December 8, 2022, and approved this final-form rulemaking.

Findings

The Department finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202), referred to as the Commonwealth Documents Law, and regulations promulgated thereunder at 1 Pa. Code §§ 7.1 and 7.2 (relating to notice of proposed rulemaking required; and adoption of regulations).

(2) A public comment period was provided as required by law and all comments were considered in drafting this final-form rulemaking.

(3) The amendment to the regulation in the manner provided by this Order is necessary and appropriate for the administration of the code.

Order

The Department, acting under the code, orders that:

(a) The regulations of the Department at 55 Pa. Code Chapter 1101 are amended by amending § 1101.51 to read as set forth in Annex A of this order, with ellipses referring to the existing text of the regulation.

(b) The Department shall submit this final-form rulemaking and Annex A to the Offices of General Counsel and Attorney General for approval as to legality and form as required by law.

(c) The Department shall submit this final-form rulemaking to IRRC and the Legislative Standing Committees as required by law.

(d) The Department shall certify and deposit this final-form rulemaking and Annex A with the Legislative Reference Bureau as required by law.

(e) This final-form rulemaking shall take effect upon final publication in the *Pennsylvania Bulletin*.

MEG SNEAD,
Acting Secretary

(*Editor's Note*: See 52 Pa.B. 8009 (December 24, 2022) for IRRC's approval order.)

Fiscal Note: Fiscal Note 14-549 remains valid for the final adoption of the subject regulation.

Annex A

TITLE 55. HUMAN SERVICES

PART III. MEDICAL ASSISTANCE MANUAL

CHAPTER 1101. GENERAL PROVISIONS

RESPONSIBILITIES

§ 1101.51. Ongoing responsibilities of providers.

* * * * *

(c) *Interrelationship of providers.* Providers are prohibited from making the following arrangements with other providers:

(1) The referral of MA recipients directly or indirectly to other practitioners or providers for financial consideration or the solicitation of MA recipients from other providers.

(2) The offering of, or paying, or the acceptance of remuneration to or from other providers for the referral of MA recipients for services or supplies under the MA Program.

(3) [Reserved].

(4) The solicitation or receipt or offer of a kickback, payment, gift, bribe or rebate for purchasing, leasing, ordering or arranging for or recommending purchasing, leasing, ordering or arranging for or recommending purchasing, leasing or ordering a good, facility, service or item for which payment is made under MA. This does not preclude discounts or other reductions in charges by a provider to a practitioner for services, that is, laboratory and x-ray, so long as the price is properly disclosed and appropriately reflected in the costs claimed or charges made by a practitioner.

(5) A participating practitioner or professional corporation may not refer a MA recipient to an independent laboratory, pharmacy, radiology or other ancillary medical service in which the practitioner or professional corporation has an ownership interest.

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[Pa.B. Doc. No. 23-48. Filed for public inspection January 13, 2023, 9:00 a.m.]