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Occupational Safety and Health Administration (OSHA): Emergency Temporary Standards (ETS) and COVID-19

Updated April 8, 2020

Congressional Research Service
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R46288

CRS REPORT
Prepared for Members and
Committees of Congress

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SUMMARY

R46288

April 8, 2020

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Occupational Safety and Health Administration (OSHA): Emergency Temporary Standards (ETS) and COVID-19

The Occupational Safety and Health Administration (OSHA) does not currently have a specific standard that protects healthcare or other workers from airborne or aerosol transmission of disease or diseases transmitted by airborne droplets. Some in Congress, and some groups representing healthcare and other workers, are calling on OSHA to promulgate an emergency temporary standard (ETS) to protect workers from exposure to SARS-Cov-2, the virus that causes Coronavirus Disease 2019 (COVID-19). The Occupational Safety and Health Act of 1970 (OSH Act) gives OSHA the ability to promulgate an ETS that would remain in effect for up to six months without going through the normal review and comment process of rulemaking. OSHA, however, has rarely used this authority in the past—not since the courts struck down its ETS on asbestos in 1983.

The California Division of Occupational Safety and Health (Cal/OSHA), which operates California's state occupational safety and health plan, has had an aerosol transmissible disease (ATD) standard since 2009. This standard includes, among other provisions, the requirement that employers provide covered employees with respirators, rather than surgical masks, when these workers interact with ATDs, such as known or suspected COVID-19 cases. Also, according to the Cal/OSHA ATD standard, certain procedures require the use of powered air purifying respirators (PAPR). Both OSHA and Cal/OSHA have issued enforcement guidance to address situations when the shortage of respirators may impede an employer's ability to comply with existing standards.

H.R. 6139, the COVID-19 Health Care Worker Protection Act of 2020, would require OSHA to promulgate an ETS on COVID-19 that incorporates both the Cal/OSHA ATD standard and the Centers for Disease Control and Prevention's (CDC's) 2007 guidelines on occupational exposure to infectious agents in healthcare settings. The CDC's 2007 guidelines generally require stricter controls than its interim guidance on COVID-19 exposure. The provisions of H.R. 6139 were incorporated into the version of H.R. 6201, the Families First Coronavirus Response Act, as introduced in the House. However, the OSHA ETS provisions were not included in the version of legislation that passed the House and the Senate and was signed into law as P.L. 116-127. A group representing hospitals claims that because SARS-Cov-2 is primarily transmitted by airborne droplets and surface contacts, surgical masks are sufficient protection for workers coming into routine contact with COVID-19 cases, and that the shortage of respirators may adversely impact some hospitals' patient capacities. H.R. 6379, as introduced by the House, also includes a requirement for an OSHA ETS and permanent standard to address COVID-19 exposure.

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Occupational Safety and Health Administration (OSHA) Standards

Section 6 of the Occupational Safety and Health Act of 1970 (OSH Act) grants the Occupational Safety and Health Administration (OSHA) of the Department of Labor (DOL) the authority to promulgate, modify, or revoke occupational safety and health standards that apply to private sector employers, the United States Postal Service, and the federal government as an employer.[1] In addition, Section 5(a)(1) of the OSH Act, commonly referred to as the General Duty Clause, requires that all employers under OSHA's jurisdiction provide workplaces free of "recognized hazards that are causing or are likely to cause death or serious physical harm" to their employees.[2] OSHA has the authority to enforce employer compliance with its standards and with the General Duty Clause through the issuance of abatement orders, citations, and civil monetary penalties. The OSH Act does not cover state or local government agencies or units. Thus, certain entities that may be affected by Coronavirus Disease 2019 (COVID-19), such as state and local government hospitals, local fire departments and emergency medical services, state prisons and county jails, and public schools, are not covered by the OSH Act or subject to OSHA regulation or enforcement.

State Plans

Section 18 of the OSH Act authorizes states to establish their own occupational safety and health plans and preempt standards established and enforced by OSHA.[3] OSHA must approve state plans if they are "at least as effective" as OSHA's standards and enforcement.[4] If a state adopts a state plan, it also must cover state and local government entities not covered by OSHA. Currently, 21 states and Puerto Rico have state plans that cover all employers, and 5 states and the U.S. Virgin Islands have state plans that cover only state and local government employers not covered by the OSH Act.[5] In the remaining states, state and local government employers are not covered by OSHA standards or enforcement. State plans may incorporate OSHA standards by reference, or states may adopt their own standards that are at least as effective as OSHA's standards.

Promulgation of OSHA Standards

OSHA may promulgate occupational safety and health standards on its own initiative or in response to petitions submitted to the agency by various government agencies, the public, or employer and employee groups.[6] OSHA is not required, however, to respond to a petition for a standard or to promulgate a standard in response to a petition. OSHA may also consult with one

[1] 29 U.S.C. §655. The provisions of the Occupational Safety and Health Act of 1970 (OSH Act) are extended to the legislative branch as an employer by the Congressional Accountability Act (P.L. 104-1).

[2] 29 U.S.C. §654(a)(1).

[3] 29 U.S.C. §667.

[4] For additional information on Occupational Safety and Health Administration (OSHA) state plans, see CRS Report R43969, *OSHA State Plans: In Brief, with Examples from California and Arizona*.

[5] Information on specific state plans is available from the OSHA website at https://www.osha.gov/stateplans.

[6] Per Section 6(b)(1) of the OSH Act [29 §655(b)(1)], a petition may be submitted by "an interested person, a representative of any organization of employers or employees, a nationally recognized standards-producing organization, the Secretary of Health and Human Services, the National Institute for Occupational Safety and Health, or a state or political subdivision."

of the two statutory standing advisory committees—the National Advisory Committee on Occupational Safety and Health (NACOSH) or the Advisory Committee on Construction Safety and Health (ACCSH)—or an ad-hoc advisory committee for assistance in developing a standard.[7]

Notice and Comment

OSHA's rulemaking process for the promulgation of standards is largely governed by the provisions of the Administrative Procedure Act (APA) and Section 6(b) of the OSH Act.[8] Under the APA informal rulemaking process, federal agencies, including OSHA, are required to provide notice of proposed rules through the publication of a Notice of Proposed Rulemaking in the *Federal Register* and provide the public a period of time to provide comments on the proposed rules.

Section 7(b) of the OSH Act mirrors the APA in that it requires notice and comment in the rulemaking process.[9] After publishing a proposed standard, the public must be given a period of at least 30 days to provide comments. In addition, any person may submit written objections to the proposed standard and may request a public hearing on the standard.

Statement of Reasons

Section 6(e) of the OSH Act requires OSHA to publish in the *Federal Register* a statement of the reasons the agency is taking action whenever it promulgates a standard, conducts other rulemaking, or takes certain additional actions, including issuing an order, compromising on a penalty amount, or settling an issued penalty.[10]

Other Relevant Laws and Executive Order 12866

In addition to the APA and OSH Act, other federal laws that generally apply to OSHA rulemaking include the Paperwork Reduction Act,[11] Regulatory Flexibility Act,[12] Congressional Review Act,[13] Information Quality Act,[14] and Small Business Regulatory Enforcement Fairness Act (SBREFA).[15] Also, Executive Order 12866, issued by President Clinton in 1993, requires agencies to submit certain regulatory actions to the Office of Management and Budget (OMB) and Office of Information and Regulatory Affairs (OIRA) for review before promulgation.[16]

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[7] The National Advisory Committee on Occupational Safety and Health (NACOSH) was established by Section 7(a) of the OSH Act [29 U.S.C. §656(a)]. The Advisory Committee on Construction Safety and Health (ACCSH) was established by Section 107 of the Contract Work Hours and Safety Act (P.L. 87-581). Section 7(b) of the OSH Act provides OSHA the authority to establish additional advisory committees.

[8] The Administrative Procedure Act (APA) is codified at 5 U.S.C. §§500-596. For detailed information on federal agency rulemaking and the APA, see CRS Report RL32240, *The Federal Rulemaking Process: An Overview*.

[9] 29 U.S.C. §655(b).

[10] 29 U.S.C §655(e).

[11] 44 U.S.C. §§3501-3520.

[12] 5 U.S.C. §§601-612.

[13] 5 U.S.C. §§801-808.

[14] 44 U.S.C. §3516 note.

[15] 5 U.S.C. §601 note. For information on these additional laws that apply to OSHA rulemaking, see U.S. Government Accountability Office (GAO), *Workplace Safety and Health: Multiple Challenges Lengthen OSHA's Standard Setting*, GAO-12-330, April 2012, Appendix II, https://www.gao.gov/products/GAO-12-330 (hereinafter cited as GAO-12-330, *Workplace Safety and Health*).

[16] Executive Order 12866, "Regulatory Planning and Review," 58 *Federal Register* 51735, October 4, 1993.

OSHA Rulemaking Timeline

OSHA rulemaking for new standards has historically been a relatively time-consuming process. In 2012, at the request of Congress, the Government Accountability Office (GAO) reviewed 59 significant OSHA standards promulgated between 1981 (after the enactments of the Paperwork Reduction Act and Regulatory Flexibility Act) and 2010.[17] For these standards, OSHA's average time between beginning formal consideration of the standard—either through publishing a Request for Information or Advanced Notice of Proposed Rulemaking in the *Federal Register* or placing the rulemaking on its semiannual regulatory agenda—and promulgation of the standard was 93 months (7 years, 9 months). Once the Notice of Proposed Rulemaking was published for these 59 standards, the average time until promulgation of the standard was 39 months (3 years, 3 months).

In 2012, OSHA's Directorate of Standards and Guidance published a flowchart of the OSHA rulemaking process on the agency's website.[18] This flowchart includes estimated duration ranges for a variety of rulemaking actions, beginning with pre-rule activities—such as developing the idea for the standard and meeting with stakeholders—and ending with promulgation of the standard. The flowchart also includes an estimated duration range for post-promulgation activities, such as judicial review. The estimated time from the start of preliminary rulemaking to the promulgation of a standard ranges from 52 months (4 years, 4 months) to 138 months (11 years, 6 months). After a Notice of Proposed Rulemaking is published in the *Federal Register,* the estimated length of time until the standard is promulgated ranges from 26 months (2 years, 2 months) to 63 months (5 years, 3 months).

Table 1 provides OSHA's estimated timelines for six major pre-rulemaking and rulemaking activities leading to the promulgation of a standard.

Table 1. OSHA Rulemaking Process: Estimated Durations of Activities

Stage	Activities	Estimated Duration
1	Preliminary rulemaking activities	12-36 months
2	Developing the proposed rule	12-36 months
3	Publishing the Notice of Proposed Rulemaking (NPRM)	2-3 months
4	Developing and analyzing the rulemaking record, including public comments and hearings	6-24 months
5	Developing the final rule, including Office of Information and Regulatory Affairs (OIRA) submission	18-36 months
6	Publishing the final rule (promulgating the new standard)	2-3 months
Total estimated duration		52-138 months
Estimated duration from NPRM to final rule		26-63 months

Source: Congressional Research Service (CRS) with data from Occupational Safety and Health Administration (OSHA), Directorate of Standards and Guidance, *The OSHA Rulemaking Process*, October 15, 2012, https://www.osha.gov/OSHA_FlowChart.pdf.

[17] GAO-12-330, *Workplace Safety and Health*.

[18] OSHA, Directorate of Standards and Guidance, *The OSHA Rulemaking Process*, October 15, 2012, https://www.osha.gov/OSHA_FlowChart.pdf.

Judicial Review

Both the APA and the OSH Act provide for judicial review of OSHA standards. Section 7(f) of the OSH Act provides that any person who is "adversely affected" by a standard may file, within 60 days of its promulgation, a petition challenging the standard with the U.S. Court of Appeals for the circuit in which the person lives or maintains his or her principal place of business.[19] A petition for judicial review does not automatically stay the implementation or enforcement of the standard. However, the court may order such a stay. OSHA estimates that post-promulgation activities, including judicial review, can take between 4 and 12 months after the standard is promulgated.[20]

Emergency Temporary Standards

Section 6(c) of the OSH Act provides the authority for OSHA to issue an Emergency Temporary Standard (ETS) without having to go through the normal rulemaking process. OSHA may promulgate an ETS without supplying any notice or opportunity for public comment or public hearings. An ETS is immediately effective upon publication in the *Federal Register*. Upon promulgation of an ETS, OSHA is required to begin the full rulemaking process for a permanent standard with the ETS serving as the proposed standard for this rulemaking. An ETS is valid until superseded by a permanent standard, which OSHA must promulgate within six months of publishing the ETS in the *Federal Register*.[21] An ETS must include a statement of reasons for the action in the same manner as required for a permanent standard. State plans are required to adopt or adhere to an ETS, although the OSH Act is not clear on how quickly a state plan must come into compliance with an ETS.

ETS Requirements

Section 6(c)(1) of the OSH Act requires that both of the following determinations be made in order for OSHA to promulgate an ETS:

- that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards, and
- that such emergency standard is necessary to protect employees from such danger.

Grave Danger Determination

The term *grave danger*, used in the first mandatory determination for an ETS, is not defined in statute or regulation. The legislative history demonstrates the intent of Congress that the ETS process "not be utilized to circumvent the regular standard-setting process," but the history is unclear as to how Congress intended the term grave danger to be defined.[22]

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[19] 29 U.S.C. §655(f).

[20] OSHA, Directorate of Standards and Guidance, *The OSHA Rulemaking Process*, October 15, 2012, https://www.osha.gov/OSHA_FlowChart.pdf.

[21] 29 U.S.C §655(c)(2).

[22] U.S. Congress, Senate Labor and Public Welfare, Subcommittee on Labor, *Legislative History of the Occupational Safety and Health Act of 1970 (*S. 2193, *P.L. 91-596)*, committee print, prepared by Subcommittee on Labor, 91st Cong., 1 sess., June 1971, 52-531 (Washington: GPO, 1971), p. 1218.

In addition, although the federal courts have ruled on challenges to previous ETS promulgations, the courts have provided no clear guidance as to what constitutes a grave danger. In 1984, the U.S. Court of Appeals for the Fifth Circuit in *Asbestos Info. Ass'n v. OSHA* issued a stay and invalidated OSHA's November 1983 ETS lowering the permissible exposure limit for asbestos in the workplace.[23] In its decision, the court stated that "gravity of danger is a policy decision committed to OSHA, not to the courts."[24] The court, however, ultimately rejected the ETS, in part on the grounds that OSHA did not provide sufficient support for its claim that 80 workers would ultimately die because of exposures to asbestos during the six-month life of the ETS.

Necessity Determination

In addition to addressing a grave danger to employees, an ETS must also be *necessary* to protect employees from that danger. In *Asbestos Info. Ass'n*, the court invalidated the asbestos ETS for the additional reason that OSHA had not demonstrated the necessity of the ETS. The court cited, among other factors, the duplication between the respirator requirements of the ETS and OSHA's existing standards requiring respirator use. The court dismissed OSHA's argument that the ETS was necessary because the agency felt that the existing respiratory standards were "unenforceable absent actual monitoring to show that ambient asbestos particles are so far above the permissible limit that respirators are necessary to bring employees' exposure within the PEL of 2.0 f/cc."[25] The court determined that "fear of a successful judicial challenge to enforcement of OSHA's permanent standard regarding respirator use hardly justifies resort to the most dramatic weapon in OSHA's enforcement arsenal."[26]

Although OSHA has not promulgated an ETS since the 1983 asbestos standard, it has since determined the necessity of an ETS. In 2006, the agency considered a petition from the United Food and Commercial Workers (UFCW) and International Brotherhood of Teamsters (IBT) for an ETS on diacetyl. The UFCW and IBT petitioned OSHA for the ETS after the National Institute for Occupational Safety and Health (NIOSH) and other researchers found that airborne exposure to diacetyl, then commonly used as an artificial butter flavoring in microwave popcorn and a flavoring in other food and beverage products, was linked to the lung disease *bronchiolitis obliterans*, now commonly referred to as "popcorn lung."[27] According to GAO's 2012 report on OSHA's standard-setting processes, OSHA informed GAO that although the agency may have been able to issue an ETS based on the grave danger posed by diacetyl, the actions taken by the food and beverage industries, including reducing or removing diacetyl from products, made it less likely that the necessity requirement could be met.[28]

ETS Duration

Section 6(c)(2) of the OSH Act provides that an ETS is effective until superseded by a permanent standard promulgated pursuant to the normal rulemaking provisions of the OSH Act. Section 6(c)(3) of the OSH Act requires OSHA to promulgate a permanent standard within six months of

[23] 727 F.2d 415, 425-427 (5th Cir. 1984).

[24] 727 F.2d 427 (5th Cir. 1984).

[25] 727 F.2d 427 (5th Cir. 1984). The ETS mandated a permissible exposure limit (PEL) for asbestos of two asbestos fibers per cubic centimeter of air (2.0 f/cc).

[26] 727 F.2d 427 (5th Cir. 1984).

[27] See, for example, Centers for Disease Control and Prevention (CDC): National Institute for Occupational Safety and Health (NIOSH), *NIOSH Alert: Preventing Lung Disease in Workers who Use or Make Flavorings*, DHHS (NIOSH) publication no. 2004–110, December 2003, https://www.cdc.gov/niosh/docs/2004-110/.

[28] GAO-12-330, *Workplace Safety and Health*.

promulgating the ETS. As shown earlier in this report, six months is well outside of historical and currently expected time frames for developing and promulgating a standard under the notice and comment provisions of the APA and OSH Act, as well as under other relevant federal laws and executive orders. This dichotomy between the statutory mandate to promulgate a standard and the timelines that, based on historical precedent, other provisions in the OSH Act might realistically require for such promulgation raises the question of whether or not OSHA could extend an ETS's duration without going through the normal rulemaking process. The statute and legislative history do not clearly address this question.

OSHA has used its ETS authority sparingly in its history and not since the asbestos ETS promulgated in 1983. As shown in **Table A-1** in the Appendix, of the nine times OSHA has issued an ETS, the courts have fully vacated or stayed the ETS in four cases and partially vacated the ETS in one case.[29] Of the five cases that were not challenged or that were fully or partially upheld by the courts, OSHA issued a permanent standard either within the six months required by the statute or within several months of the six month period and always within one year of the promulgation of the ETS.[30] Each of these cases, however, occurred before 1980, when a combination of additional federal laws and court decisions added additional procedural requirements to the OSHA rulemaking process. OSHA did not attempt to extend the ETS's expiration date in any of these cases.

Although the courts have not ruled directly on an attempt by OSHA to solely extend the life of an ETS, in 1974, the U.S. Court Appeals for the Fifth Circuit held in *Florida Peach Growers Ass'n v. United States Department of Labor* that OSHA was within its authority to amend an ETS without going through the normal rulemaking process.[31] The court stated that "it is inconceivable that Congress, having granted the Secretary the authority to react quickly in fast-breaking emergency situations, intended to limit his ability to react to developments subsequent to his initial response."[32] The court also recognized the difficulty OSHA may have in promulgating a standard within six months due to the notice and comment requirements of the OSH Act, stating that in the case of OSHA seeking to amend an ETS to expand its focus, "adherence to subsection (b) procedures would not be in the best interest of employees, whom the Act is designed to protect. Such lengthy procedures could all too easily consume all of the temporary standard's six months life"[33]

[29] Mark A. Rothstein, "Substantive and Procedural Obstacles to OSHA Rulemaking: Reproductive Hazards as an Example," *Boston College Environmental Affairs Law Review*, vol. 12, no. 4 (August 1985), p. 673.

[30] For example, OSHA promulgated the Acrylonitrile (vinyl cyanide) ETS on January 17, 1978, and the permanent standard on October 3, 1978, with an effective date of November 2, 1978. The preamble to the permanent standard published in the *Federal Register* does not include information on the status of the ETS during the time between its expiration and the promulgation of the permanent standard. OSHA, "Occupational Exposure to Acrylonitrile (Vinyl Cyanide)," 43 *Federal Register* 45762, October 3, 1978.

[31] 489 F.2d. 120 (5th Cir. 1974).

[32] 489 F.2d. 127 (5th Cir. 1974).

[33] 489 F.2d. 127 (5th Cir. 1974).

OSHA Standards Related to COVID-19

Current OSHA Standards

Currently, no OSHA standard directly covers exposure to airborne or aerosol diseases in the workplace. As a result, OSHA is limited in its ability to enforce protections for healthcare and other workers who may be exposed to SARS-Cov-2, the virus that causes COVID-19.[34]

OSHA may enforce the General Duty Clause in the absence of a standard, if it can be determined that an employer has failed to provide a worksite free of "recognized hazards" that are "causing or are likely to cause death or serious physical harm" to workers.[35] In addition, OSHA's standards for the use of personal protective equipment (PPE) may apply in cases in which workers require eye, face, hand, or respiratory protection against COVID-19 exposure.[36]

OSHA Respiratory Protection Standard

National Institute for Occupational Safety and Health Certification

The OSHA respiratory protection standard requires the use of respirators certified by NIOSH in cases in which engineering controls, such as ventilation or enclosure of hazards, are insufficient to protect workers from breathing contaminated air.[37] Surgical masks, procedure masks, and dust masks are not considered respirators. NIOSH certifies respirators pursuant to federal regulations.[38] For nonpowered respirators, such as filtering face piece respirators commonly used in healthcare and construction, NIOSH classifies respirators based on their efficiency at filtering airborne particles and their ability to protect against oil particles. Under the NIOSH classification system, the letter (N, R, or P) indicates the level of oil protection as follows: N—no oil protection; R—oil resistant; and P—oil proof. The number following the letter indicates the efficiency rating of the respirator as follows: 95—filters 95% of airborne particles; 97—filters 97% of airborne particles; and 100—filters 99.7% of airborne particles. Thus an N95 respirator, the most common type, is one that does not protect against oil particles and filters out 95% of airborne particles. An R or P respirator can be used in place of an N respirator.

A respirator that is past its manufacturer-designated shelf life is no longer considered to be certified by NIOSH. However, in response to potential shortages in respirators, NIOSH has tested and approved certain models of respirators for certified use beyond their manufacturer-designated shelf lives.[39]

Respirators designed for certain medical and surgical uses are subject to both certification by NIOSH (for oil protection and efficiency) and regulation by the Food and Drug Administration (FDA) as medical devices. In general, respirators with exhalation valves cannot be used in

[34] OSHA has a standard on blood-borne pathogens (29 C.F.R. §1910.1030) but does not have a standard on pathogens transmitted by airborne droplets.

[35] 29 U.S.C. §654(a)(1).

[36] 29 C.F.R. §§1910.133, 1910.134, and 1910.138.

[37] 29 C.F.R. §1910.134.

[38] 42 C.F.R. Part 84,

[39] NIOSH, *Release of Stockpiled Filtering Facepiece Respirators Beyond the Manufacturer-Designated Shelf Life: Considerations for the COVID-19 Response*, February 28, 2020, https://www.cdc.gov/coronavirus/2019-ncov/release-stockpiled-N95.html.

surgical and certain medical settings because, although the presence of an exhalation valve does not affect the respirator's protection afforded the user, it may allow unfiltered air from the user into a sterile field. On March 2, 2020, FDA issued an Emergency Use Authorization (EUA) to approve for use in medical settings certain NIOSH-certified respirators not previously regulated by FDA.[40]

CDC Interim Guidance on Respiratory Protection

On March 10, 2020, the Centers for Disease Control and Prevention (CDC) updated its interim guidance for the protection of healthcare workers against exposure to COVID-19 to permit healthcare workers caring for known or suspected COVID-19 cases to use "facemasks" when respirators are not available or are in limited supply.[41] This differs from the CDC's 2007 guidelines for control of infectious agents in healthcare settings, which required the use of respirators for treatment of known or suspected cases.[42] CDC states that respirators should be prioritized for use in medical procedures likely to generate respiratory aerosols. Before this interim guidance was released, Representative Bobby Scott, Chairman of the House Committee on Education and Labor, and Representative Alma Adams, Chair of the Subcommittee on Workforce Protections, sent a letter to Secretary of Health and Human Services (HHS) Alex M. Azar II expressing their opposition to this change in the interim standard.[43]

Medical Evaluation and Fit Testing

The OSHA respiratory protection standard requires that the employer provide a medical evaluation to the employee to determine if the employee is physiologically able to use a respirator. This medical evaluation must be completed before any fit testing. For respirators designed to fit tightly against the face, the specific type and model of respirator that an employee is to use must be fit tested in accordance with the procedures provided in Appendix A of the OSHA respiratory protection standard to ensure there is a complete seal around the respirator when worn.[44] Once an employee has been fit tested for a respirator, he or she is required to be fit tested annually or whenever the model of respirator, but not the actual respirator itself, is changed. Each time an individual uses a respirator, he or she is required to perform a check of the seal of the respirator to his or her face in accordance with the procedures provided in Appendix B

[40] Letter from RADM Denise M. Hinton, chief scientist, Food and Drug Administration (FDA), to Robert R. Redfield, Director, CDC, March 2, 2020, https://www.fda.gov/media/135763/download. The list of respirators approved under this Emergency Use Authorization (EUA) is in Appendix B to this letter, updated at https://www.fda.gov/media/135921/download.

[41] Although the interim guidance does not specifically define the term *facemask*, it does differentiate between a facemask and a respirator such that any recommendation to use a facemask does not require the use of a respirator. CDC, *Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings*, updated March 10, 2020, https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html.

[42] CDC, *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings*, updated July 2019, https://www.cdc.gov/infectioncontrol/pdf/guidelines/isolation-guidelines-H.pdf.

[43] Letter from Representative Robert C. "Bobby" Scott, chairman, House Committee on Education and Labor, and Representative Alma S. Adams, chair, Subcommittee on Workforce Protections, to The Honorable Alex M. Azar II, Secretary of Health and Human Services (HHS), March 9, 2020, https://edlabor.house.gov/imo/media/doc/Azar%20Redfield%20Letter_SIGNED%202020-03-09.pdf.

[44] 29 C.F.R. §1910.134 Appendix A. Powered air purifying respirators (PAPR) that do not require a seal to the user's face do not need to be fit tested.

of the standard.[45] On March 14, 2020, OSHA issued guidance permitting employers to suspend annual fit testing of respirators for employees that have already been fit tested on the same model respirator.

Temporary OSHA Enforcement Guidance on the Respiratory Protection Standard

In response to shortages of respirators and other PPE during the national response to the COVID-19 pandemic, OSHA has issued three sets of temporary enforcement guidance to permit the following exceptions to the respiratory protection standard:

1. Employers may suspend annual fit testing of respirators for employees that have already been fit tested on the same model respirator; [46]
2. Employers may permit the use of expired respirators and the extended use or reuse of respirators, provided the respirator maintains its structural integrity and is not damaged, soiled, or contaminated (e.g., with blood, oil, or paint);[47] and
3. Employers may permit the use of respirators not certified by NIOSH, but approved under standards used by the following countries or jurisdictions, in accordance with the protection equivalency tables provided in Appendices A and B of the enforcement guidance document:
    - Australia,
    - Brazil,
    - European Union,
    - Japan,
    - Mexico,
    - People's Republic of China, and
    - Republic of Korea.[48]

Cal/OSHA Aerosol Transmissible Disease Standard

Although no OSHA standard specifically covers aerosol or airborne disease transmission, the California Division of Occupational Safety and Health (Cal/OSHA), under its state plan, promulgated its aerosol transmissible disease (ATD) standard in 2009.[49] The ATD standard covers most healthcare workers, laboratory workers, as well as workers in correctional facilities, homeless shelters, and drug treatment programs. Under the ATD standard, SARS-Cov-2, the virus

[45] 29 C.F.R. §1910.134 Appendix B.

[46] OSHA, *Temporary Enforcement Guidance - Healthcare Respiratory Protection Annual Fit-Testing for N95 Filtering Facepieces During the COVID-19 Outbreak*, March 14, 2020, https://www.osha.gov/memos/2020-03-14/temporary-enforcement-guidance-healthcare-respiratory-protection-annual-fit.

[47] OSHA, *Enforcement Guidance for Respiratory Protection and the N95 Shortage Due to the Coronavirus Disease 2019 (COVID-19) Pandemic*, April 3, 2020, https://www.osha.gov/memos/2020-04-03/enforcement-guidance-respiratory-protection-and-n95-shortage-due-coronavirus. Under this guidance, employers are required to address in their written respiratory protection plans when respirators are contaminated and not available for use or reuse.

[48] OSHA, *Enforcement Guidance for Use of Respiratory Protection Equipment Certified under Standards of Other Countries or Jurisdictions During the Coronavirus Disease 2019 (COVID-19) Pandemic*, April 3, 2020, https://www.osha.gov/memos/2020-04-03/enforcement-guidance-use-respiratory-protection-equipment-certified-under.

[49] Cal. Code Regs. tit. 8, §5199.

that causes COVID-19, is classified as a disease or pathogen requiring airborne isolation. This classification subjects the virus to stricter control standards than diseases requiring only droplet precautions, such as seasonal influenza.[50] The key requirements of the ATD standard include

- written ATD exposure control plan and procedures,
- training of all employees on COVID-19 exposure, use of PPE, and procedures if exposed to COVID-19,
- engineering and work practice controls to control COVID-19 exposure, including the use of airborne isolation rooms,
- provision of medical services to employees, including removal of exposed employees,
- specific requirements for laboratory workers, and
- PPE requirements.

Cal/OSHA Aerosol Transmissible Disease PPE Requirements

The Cal/OSHA ATD standard requires that employers provide employees PPE, including gloves, gowns or coveralls, eye protection, and respirators certified by NIOSH at least at the N95 level whenever workers

- enter or work in an airborne isolation room or area with a case or suspected case;
- are present during procedures or services on a case or suspected case;
- repair, replace, or maintain air systems or equipment that may contain pathogens;
- decontaminate an area that is or was occupied by a case or suspected case;
- are present during aerosol generating procedures on cadavers of cases or suspected cases;
- transport a case or suspected case within a facility or within a vehicle when the patient is not masked; and
- are working with a viable virus in the laboratory.[51]

In addition, a powered air purifying respirator (PAPR) with a high-efficiency particulate air (HEPA) filter must be used whenever a worker performs a *high-hazard procedure* on a known or suspected COVID-19 case.[52] High-hazard procedures are those in which "the potential for being exposed to aerosol transmissible pathogens is increased due to the reasonably anticipated generation of aerosolized pathogens"—they include intubation, airway suction, and caring for patients on positive pressure ventilation.[53] Emergency medical services (EMS) workers may use N100, R100, or P100 respirators in place of PAPRs.

[50] Cal. Code Regs. tit. 8, §5199 Appendix A.

[51] California Division of Occupational Safety and Health (Cal/OSHA), *Interim Guidance for Protecting Health Care Workers from Exposure to Coronavirus Disease (COVID-19)*, March 2020, https://www.dir.ca.gov/dosh/Coronavirus-info.html.

[52] A PAPR uses a mechanical device to draw in room air and filter it before expelling that air over the user's face. In general, PAPRs do not require a tight seal to the user's face and do not need to be fit tested.

[53] Cal. Code Regs. tit. 8, §5199(b).

Cal/OSHA Interim Guidance on COVID-19

Cal/OSHA has issued interim guidance in response to shortages of respirators in the state due to the COVID-19 pandemic response.[54] Under this interim guidance, if the supply of N95 respirators or PAPRs are insufficient to meet current or anticipated needs, surgical masks may be used for low-hazard patient contacts that would otherwise require the use of respirators, and respirators may be used for high-hazard procedures that would otherwise require the use of PAPRs.

OSHA Infectious Disease Standard Rulemaking

In 2010, OSHA published a Request for Information in the *Federal Register* seeking public comments on strategies to control exposure to infectious diseases in healthcare workplaces.[55] After collecting public comments and holding public meetings, OSHA completed the SBREFA process in 2014. Since then, however, no public actions have occurred on this rulemaking; since the spring of 2017, this rulemaking has been listed as a "long-term action" in DOL's semiannual regulatory agenda.

Congressional Activity to Require an OSHA Emergency Temporary Standard on COVID-19

On March 5, 2020, Representative Scott, chairman of the House Committee on Education and Labor, and Representative Adams, chair of the Subcommittee on Workforce Protections, sent a letter to Secretary of Labor Eugene Scalia calling on OSHA to promulgate an ETS to address COVID-19 exposure among healthcare workers.[56] This letter followed an earlier letter from January requesting that OSHA reopen its rulemaking on the infectious disease standard and begin to formulate for possible future promulgation an ETS to address COVID-19 exposure.[57] Senator Patty Murray, ranking member of the Senate Committee on Health, Education, Labor, and Pensions and a group of Democratic Senators, sent a similar letter to the Secretary of Labor calling for an OSHA ETS.[58]

In addition, in March 2020, David Michaels, who served as the Assistant Secretary of Labor for Occupational Safety and Health during the Obama Administration, wrote an op-ed in *The Atlantic* calling on OSHA to promulgate a COVID-19 ETS.[59] On March 6, 2020, the AFL-CIO and 22 other unions petitioned OSHA for an ETS on COVID-19 that would cover all workers with

[54] California Division of Occupational Safety and Health (Cal/OSHA), *Cal/OSHA Interim Guidance on COVID-19 for Health Care Facilities: Severe Respirator Supply Shortages*, March 28, 2020, https://www.dir.ca.gov/dosh/coronavirus/Cal-OSHA-Guidance-for-respirator-shortages.pdf.

[55] OSHA, "Infectious Diseases," 75 *Federal Register* 24835, May 6, 2010.

[56] Letter from Representative Scott, chairman, House Committee on Education and Labor, and Representative Adams, chair, Subcommittee on Worker Protections, to The Honorable Eugene Scalia, Secretary of Labor, March 5, 2020, https://edlabor.house.gov/imo/media/doc/2020-03-05%20OSHA%20ETS%20Letter.pdf.

[57] Letter from Representative Scott, chairman, House Committee on Education and Labor, and Representative Adams, chair, Subcommittee on Worker Protections, to The Honorable Eugene Scalia, Secretary of Labor, January 30, 2020, https://edlabor.house.gov/imo/media/doc/2020-01-30%20RCS%20to%20DOL%20Corona%20Letter_SIGNED1.pdf.

[58] Letter from Senator Patty Murray, ranking member, Senate Committee on Health, Education, Labor, and Pensions, Senator Robert Menendez, and Senator Tammy Baldwin, et al. to The Honorable Eugene Scalia, Secretary of Labor, March 9, 2020, https://www.baldwin.senate.gov/imo/media/doc/20200309%20OSHA%20ETS%20Letter.pdf.

[59] David Michaels, "What Trump Could Do Right Now to Keep Workers Safe From the Coronavirus," *The Atlantic*, March 2, 2020, https://www.theatlantic.com/ideas/archive/2020/03/use-osha-help-stem-covid-19-pandemic/607312/.

potential exposures.[60] National Nurses United submitted a similar petition requesting that OSHA promulgate an ETS based largely on the Cal/OSHA ATD standard.[61]

H.R. 6139, the COVID-19 Health Care Worker Protection Act of 2020

On March 9, 2019, Representative Scott introduced H.R. 6139, the COVID-19 Health Care Worker Protection Act of 2020. This bill would require OSHA to promulgate a COVID-19 ETS within one month of enactment. The ETS would be required to cover healthcare workers and any workers in sectors determined by the CDC or OSHA to be at an elevated risk of COVID-19 exposure. The ETS would be required to include an exposure control plan provision and be, at a minimum, based on CDC's 2007 guidance and any updates to this guidance. The ETS would also be required to provide no less protection than any state standard on novel pathogens, thus requiring OSHA to include the elements of the Cal/OSHA ATD standard in this ETS. Title II of the bill would provide that hospitals and skilled nursing facilities that receive Medicare funding and that are owned by state or local government units and not subject to state plans would be required to comply with the ETS.

P.L. 116-127, the Families First Coronavirus Response Act

The provisions of H.R. 6139 were included as Division C of H.R. 6201, the Families First Coronavirus Response Act, as introduced in the House. The American Hospital Association (AHA) issued an alert to its members expressing its opposition to the OSHA ETS provisions in the bill.[62] Specifically, the AHA opposed the requirement that the ETS be based on the CDC's 2007 guidance. The AHA stated that unlike severe acute respiratory syndrome (SARS), which was transmitted through the air, COVID-19 transmission is through droplets and surface contacts. Thus, the requirement of the 2007 CDC guidance that N95 respirators, rather than surgical masks, be used for patient contact is not necessary to protect healthcare workers from COVID-19, and the use of surgical masks is consistent with World Health Organization guidance. The AHA also claimed that shortages of available respirators could reduce the capacity of hospitals to treat COVID-19 patients, due to a lack of respirators for staff. The OSHA ETS provisions were not included in the version of the legislation that was passed by the House and the Senate and signed into law as P.L. 116-127.

H.R. 6379, the Take Responsibility for Workers and Families Act

Division D of H.R. 6379, the Take Responsibility for Workers and Families Act, as introduced in the House on March 23, 2020, includes the requirement that OSHA promulgate an ETS on COVID-19 within seven days of enactment and a permanent COVID-19 standard within 24 months of enactment to cover healthcare workers, firefighters and emergency response workers, and workers in other occupations that CDC or OSHA determines to have an elevated risk of

[60] Letter from Richard L. Trumka, president, AFL-CIO, to The Honorable Eugene Scalia, Secretary of Labor, March 6, 2020, https://aflcio.org/statements/petition-secretary-scalia-osha-emergency-temporary-standard-infectious-disease.

[61] Letter from Bonnie Castillo, executive director, National Nurses United, to The Honorable Eugene Scalia, Secretary of Labor, and The Honorable Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, March 4, 2020, https://act.nationalnursesunited.org/page/-/files/graphics/NNUPetitionOSHA03042020.pdf.

[62] Emily Kopp, "Hospitals want to kill a policy shielding nurses from COVID-19 because there aren't enough masks," *Roll Call*, March 3, 2020, https://www.rollcall.com/2020/03/13/hospitals-want-to-kill-a-policy-shielding-nurses-from-covid-19-because-there-arent-enough-masks/. This alert is available to American Hospital Association (AHA) members on the AHA website at https://www.aha.org.

COVID-19 exposure. Division D of H.R. 6379 would amend the OSH Act, for the purposes of the ETS only, such that state and local government employers in states without state plans would be covered by the ETS.

This legislation would specifically provide that the ETS would remain in force until the permanent standard is promulgated and explicitly exempts the ETS from the Regulatory Flexibility Act, Paperwork Reduction Act, and Executive Order 12866. OSHA would be granted enforcement discretion in cases in which it is not feasible for an employer to fully comply with the ETS (such as a case in which PPE is unavailable) if the employer is exercising due diligence to comply and implementing alternative means to protect employees.

Like the provisions in H.R. 6139 and the version of H.R. 6201 introduced in the House, this ETS and permanent standard would be required to include an exposure control plan and provide no less protection than any state standard on novel pathogens, thus requiring OSHA to include the elements of the Cal/OSHA ATD standard in this ETS and permanent standard. Although the ETS provisions in H.R. 6139 and H.R. 6201 required that the ETS be based on the 2007 CDC guidance, specific reference to the 2007 guidance is not included in this legislation. Rather, the ETS and permanent standard would have to incorporate, as appropriate, "guidelines issued by the Centers for Disease Control and Prevention, and the National Institute for Occupational Safety and Health, which are designed to prevent the transmission of infectious agents in healthcare settings" and scientific research on novel pathogens.

States with occupational safety and health plans would be required to adopt the ETS, or their own ETSs at least as effective as the ETS, within 14 days of the legislation's enactment.

Appendix.

Table A-1. OSHA Emergency Temporary Standards (ETS)

Year	Subject of ETS	*Federal Register* Citation of ETS	Result of Judicial Review	Judicial Review Case Citation
1971	Asbestos	36 *Federal Register* 23207 (December 7, 1971)	Not challenged	—
1973	Organophosphorous pesticides	38 *Federal Register* 10715 (May 1, 1973); amended by 38 *Federal Register* 17214 (June 29, 1973)	Vacated	*Florida Peach Growers Ass'n v. United States Department of Labor,* 489 F.2d 120 (5th Cir. 1974)
1973	Fourteen carcinogens	38 *Federal Register* 10929 (May 3, 1973)	Twelve upheld, two vacated	*Dry Color Mfrs. Ass'n v. Department of Labor,* 486 F.2d 98 (3d Cir. 1973)
1974	Vinyl chloride	39 *Federal Register* 12342 (April 5, 1974)	Not challenged	—
1976	Diving operations	41 *Federal Register* 24271 (June 15, 1976)	Stayed	*Taylor Diving & Salvage Co. v. Department of Labor*, 537 F.2d 819 (5th Cir. 1976)
1977	Benzene	42 *Federal Register* 22515 (May 3, 1977)	Stayed	*Industrial Union Dep't v. Bingham*, 570 F.2d 965 (D.C. Cir. 1977)
1977	1,2 Dibromo-3-chloropropane (DBCP)	42 *Federal Register* 45535 (September 9, 1977)	Not challenged	—
1978	Acrylonitrile (vinyl cyanide)	43 *Federal Register* 2585 (January 17, 1978)	Stay denied	*Vistron v. OSHA*, 6 OSHC 1483 (6th Cir. 1978)
1983	Asbestos	48 *Federal Register* 51086 (November 4, 1983)	Stayed	*Asbestos Info. Ass'n v. OSHA*, 727 F.2d 415 (5th Cir. 1984)

Source: CRS with data from Mark A. Rothstein, "Substantive and Procedural Obstacles to OSHA Rulemaking: Reproductive Hazards as an Example," *Boston College Environmental Affairs Law Review*, vol. 12, no. 4 (August 1985), p. 673.

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