May 20, 2025

The Honorable Mehmet Oz, M.D.
Administrator
U.S. Department of Health and Human Services
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Petition to CMS to Implement Work-Hour Regulations for All Resident Physicians

Dear Administrator Oz,

Public Citizen, a consumer advocacy organization with more than 500,000 members and supporters nationwide and the American Medical Student Association (AMSA), an international organization representing over 30,000 physicians-in-training, hereby petition the Centers for Medicare and Medicaid Services (CMS) to implement the following key regulations for the work hours of resident physicians in all residency and subspecialty fellowship programs, which are similar but not identical to the recommendations put forth in the 2009 report *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety* by the Institute of Medicine (IOM, which in 2015 was renamed National Academy of Medicine; for additional details, see Table 1):[1]

(1) A limit of 80 hours of work in each and every workweek, without averaging;
(2) A limit of 16 consecutive hours worked in one shift for *all* resident physicians and subspecialty resident physicians, with no exceptions;
(3) At least one 24-hour period of time off work per week (no averaging) and one 48-hour period of time off work per month, no averaging;
(4) In-hospital on-call frequency no more than once every three nights, no averaging;
(5) A minimum of at least 10 hours off work after a day shift and a minimum of 12 hours off work after a night shift; and
(6) A maximum of four consecutive night shifts with a minimum of 48 hours off after a sequence of three or four night shifts.

[1] Institute of Medicine. Committee on Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedule to Improve Patient Safety, National Research Council. Resident Duty Hours: Enhancing Sleep, Supervision, and Safety. Ulmer C, Miller Wolman D, Johns MME, editors. Washington (DC): The National Academies Press; 2009.

Work hours include any time asleep at the work site. Time off work is time away from the hospital or other work site while not on call. As stated by the Accreditation Council for Graduate Medical Education (ACGME), any time resident physicians spend on "at-home call must count toward the 80-hour maximum weekly limit."[2]

Table 1: Comparison of Petitioners' Request and the IOM Recommendations

	IOM Recommendations[3]	**Petitioner's Request**
Maximum hours of work per week	80 per week, averaged over four weeks.	80 hours per week, **no averaging**
Maximum shift length	30 hours, including a five-hour protected sleep period between 10 pm and 8 am. Without a protected, uninterrupted, continuous sleep period, 16 hours.	16 hours, **no exceptions**
Mandatory time off duty	One 24-hour period off per week, no averaging; one 48-hour period off per month	At least one 24-hour period off per week (no averaging), one 48-hour period off per month **(no averaging)**
Maximum in-hospital on-call frequency	Every third night, no averaging	**No more than once** every three nights, no averaging
Minimum time off between shifts	A minimum of 10 hours after a day shift that is not part of an extended period; a minimum of 12 hours after a night shift that is not part of an extended duty period; a minimum of 14 hours after an extended duty period	At least 10 hours off work after a day shift and a minimum of 12 hours off work after a night shift. **No extended work shifts.**
Maximum frequency of in-hospital night shifts	Four night shifts; 48 hours off after three or four nights of consecutive duty	Four consecutive night shifts **with a minimum** of 48 hours off after a sequence of three-four night shifts.

We are not asking CMS to assume oversight of resident physician education and supervision; these are the continuing responsibilities of the ACGME.

[2] Accreditation Council for Graduate Medical Education. ACGME common program requirements (residency). September 17, 2022. https://www.acgme.org/globalassets/pfassets/programrequirements/cprresidency_2023.pdf. Accessed April 25, 2025.

[3] Institute of Medicine. Committee on Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedule to Improve Patient Safety, National Research Council. Resident Duty Hours: Enhancing Sleep, Supervision, and Safety. Ulmer C, Miller Wolman D, Johns MME, editors. Washington (DC): The National Academies Press; 2009.

In this petition we define resident physicians as physicians "who have graduated from medical school and are pursuing specialization."[4] As will be discussed in detail below, evidence convincingly demonstrates that these recommendations are necessary to protect the safety of resident physicians. These work-hour regulations should also help to reduce medical errors and contribute to a safer, better standard of care for patients nationwide.

[4] Accreditation Council for Graduate Medical Education. Physician education. https://www.acgme.org/about/physician-education/. Accessed April 25, 2025.

Contents

Part 1: Resident Physicians Work Excessive Hours

Long work hours for resident physicians have long been depicted by some not only as a way to prepare junior doctors for "an occupation that requires hard work and dedication,"[5] but also as a "rite of passage" that needs to be endured.[6] In fact, the term "resident physician" itself refers to the fact that medical trainees were once required to stay at the hospital for their entire postgraduate training.[7] The origin of this practice may in part be responsible for the belief held by some that long hours are still an integral and necessary part of medical training, despite substantial evidence to the contrary.

To this day, resident physicians regularly work at least 80 hours a week, and often much longer. They also frequently work shifts of 28 consecutive hours or more, during which they get no or only very little sleep.[8,9] Such long shifts are called "extended shifts," although the Occupational Safety and Health Administration (OSHA) states that any work shift that is longer than "eight consecutive hours during the day, five days a week with at least an eight-hour rest" should be considered "extended or unusual"[10] in the context of medical residency programs, extended shifts usually refer to shifts that are 24 hours or longer. In this petition we use the term "extended shift" to refer to the latter.

A U.S. nationwide prospective cohort study published in 2023 found that 9.7% of resident physicians regularly worked more than 80 hours a week.[11] Moreover, each month, resident physicians tended to work an average of 1.6 extended-duration shifts of more than 24 hours where they obtained only about 2.5 hours of sleep on average, and during about 14% of these extended duration shifts, resident physicians did not obtain any sleep.

There is a substantial and growing body of evidence demonstrating that such long work hours and extended shifts are associated with sleep deprivation and fatigue. Moreover, acute and chronic sleep deprivation has been shown to have a detrimental impact on the health and safety of resident physicians and the patients under their care.[12] For example, sleep deprivation places

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[5] Philibert I, Taradejna C. A brief history of duty hours and resident education. In: Philibert I, Amis Jr S, Vasilou E. ACGME task force on quality care and professionalism: The ACGME 2011 duty hour standard. Enhancing Quality of Care, Supervision, and Resident Professional Development. Chicago, IL; 2011: 5-11.

[6] Papp KK, Stoller EP, Sage P, et al. The effects of sleep loss and fatigue on resident-physicians: a multi-institutional, mixed-method study. *Acad Med*. 2004;79(5):394-406.

[7] Czeisler CA, Weaver MD, Landrigan CP, et al. Extended work hours increase risk of harm, regardless of resident physicians' experience levels. *BMJ*. 2023;381(April 13):838.

[8] Landrigan CP, Barger LK, Cade BE, et al. Interns' compliance with accreditation council for graduate medical education work-hour limits. *JAMA.* 2006;296(9):1063-1070.

[9] Schlick CJ, Hewitt DB, Quinn CM, et al. A national survey of motor vehicle crashes among general surgery residents. *Ann Surg*. 2021;274(6):1001-1008.

[10] Occupational Safety and Health Administration. Extended/unusual work shifts guide. https://www.osha.gov/emergency-preparedness/guides/extended-unusual-work-shifts. Accessed April 25, 2025.

[11] Barger LK, Weaver MD, Sullivan JP, et al. Impact of work schedules of senior resident physicians on patient and resident physician safety: nationwide, prospective cohort study. *BMJ Med.* 2023;2(1):e000320.

[12] *Ibid.*

resident physicians at an increased risk of being involved in fatigue-related motor vehicle crashes and near misses,[13] negatively affects their mental health,[14] increases the risk of percutaneous (needlestick) injuries,[15] and increases the risk of obstetric complications in pregnant resident physicians.[16] At the same time, impaired sleep associated with long work hours has been linked to increased medical errors and preventable adverse events, leading to worse patient safety outcomes.[17]

Despite these findings, the necessity for long, grueling work hours during medical residency and whether and to what degree work hours should be reduced have continued to be hotly debated topics for decades. Moreover, unlike for employees in other occupations, no federal agency ensures the right of resident physicians to a safe and healthful workplace.

Based on the lack of federal regulations and the serious safety concerns for resident physicians and patients associated with the work-hour standards for resident physicians in the United States, Public Citizen's Health Research Group and co-petitioners filed petitions to OSHA in 2001[18] and again in 2010,[19] each time requesting work-hour limitations that are largely in line with the recommendations outlined in the influential 2009 IOM report (although in 2001, the maximum shift length requested by the petitioners was 24 hours, not 16 hours as requested in the 2010 and current petition).[20]

Unfortunately, OSHA denied both petitions, although the agency shared the petitioners' concerns over resident physicians' health and safety.[21] The 2001 petition was denied about one-and-a-half years after we filed it, in part because OSHA stated that the agency was already fully committed to addressing other important workplace and health issues. Moreover, OSHA argued that because a report that the ACGME had just endorsed and that addressed the key concerns highlighted in the petition, "the ACGME and other entities are well suited to address work-duty restrictions of medical residents and fellows."

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[13] Freedman-Weiss MR, Heller DR, White EM, et al. Driving safety among surgical residents in the era of duty hour restrictions. *J Surg Educ*. 2021;78(3):770-776.
[14] Martini S, Arfken CL, Balon R. Comparison of burnout among medical residents before and after the implementation of work hours limits. *Acad Psychiatry*. 2006;30(4):352-355.
[15] Sethi N, Evans D, Murray A. Needlestick occurrences and reporting among residents in the operative setting. *J Surg Educ*. 2020;77(6):1542-1551.
[16] Behbehani S, Tulandi T. Obstetrical complications in pregnant medical and surgical residents. *J Obstet Gynaecol Can*. 2015;37(1):25-31.
[17] Weaver MD, Landrigan CP, Sullivan JP, et al. National improvements in resident physician-reported patient safety after limiting first-year resident physicians' extended duration work shifts: a pooled analysis of prospective cohort studies. *BMJ Qual Saf*. 2022;32(2):81-89.
[18] Public Citizen. Petition requesting medical residents work hour limits. April 30, 2001. https://www.citizen.org/article/petition-requesting-medical-residents-work-hour-limits/. Accessed April 25, 2025.
[19] Public Citizen. Petition to reduce medical resident work hours. September 2, 2010. https://www.citizen.org/article/petition-to-reduce-medical-resident-work-hours-2/. Accessed April 25, 2025.
[20] Institute of Medicine. Committee on Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedule to Improve Patient Safety, National Research Council. Resident Duty Hours: Enhancing Sleep, Supervision, and Safety. Ulmer C, Miller Wolman D, Johns MME, editors. Washington (DC): The National Academies Press; 2009.
[21] Public Citizen. Letter responding to OSHA's denial of resident work hours petition. November 3, 2011. https://www.citizen.org/article/letter-responding-to-oshas-denial-of-resident-work-hours-petition/. Accessed April 25, 2025.

Although the ACGME implemented its first work-hour regulation in 2003, it fell short of the limitations the petitioners argue to be necessary to protect the health and safety of resident physicians and patients.[22] They were also not adequately enforced by the ACGME.[23] For this reason, Public Citizen and co-petitioners again filed a petition to OSHA in 2010. OSHA again denied the petition, a year after it was submitted, in part because the ACGME had just implemented updated work-hour regulations in 2011 (which also fell short of the petitioners' request).[24] The agency again stated that the petition was filed "at a time when the Agency faces significant challenges."

In 2017 the ACGME again implemented new work-hour regulations that rolled back some of the protections the ACGME had put in place for first-year resident physicians in 2011. For this reason, the work-hour standard has in fact deteriorated since the last Public Citizen petition was filed. At the same time, as detailed below, more evidence has demonstrated that the current ACGME work-hour regulations do not ensure a safe and healthful workplace for resident physicians and a safe standard of care for patients.

Public Citizen and the American Medical Student Association therefore petition CMS to implement an evidence-based federal work-hour standard that will 1) ensure a humane and safe work environment for resident physicians and 2) ensure that patients are not harmed by excessive work hours of resident physicians.

1.1. The history of work-hour regulations in the United States

Since the beginning of the 20th century, various organizations have accredited medical residency programs. However, none of these organizations regulated work hours for resident physicians.[25] In fact, although the negative effect of extended work hours on patient outcomes had long been demonstrated,[26, 27] it was only after Libby Zion, a college student, died while hospitalized in a New York City teaching hospital in 1984 that the issue gained wider attention.[28]

At the time, a grand jury investigation found that the 36-hour shifts worked by the resident physicians who cared for Libby Zion had contributed to her death and called for a reform of

[22] Accreditation Council for Graduate Medical Education (ACGME). The ACGME's approach to limit resident duty hours 12 months after implementation: a summary of achievements. https://www.acgme.org/globalassets/pfassets/publicationspapers/dh_dutyhoursummary2003-04.pdf. Accessed April 25, 2025.

[23] Landrigan CP, Barger LK, Cade BE, et al. Interns' compliance with accreditation council for graduate medical education work-hour limits. *JAMA.* 2006;296(9):1063-1070.

[24] Public Citizen. Letter responding to OSHA's denial of resident work hours petition. November 3, 2011. https://www.citizen.org/article/letter-responding-to-oshas-denial-of-resident-work-hours-petition/. Accessed April 25, 2025.

[25] Philibert I, Taradejna C. A brief history of duty hours and resident education. In: Philibert I, Amis Jr S, Vasilou E. ACGME task force on quality care and professionalism: The ACGME 2011 duty hour standard. Enhancing Quality of Care, Supervision, and Resident Professional Development. Chicago, IL; 2011: 5-11.

[26] Friedman RC, Bigger JT, Kornfeld DS. The intern and sleep loss. *N Engl J Med.* 1971;285(4):201-203.

[27] Weaver MD, Sullivan JP, Landrigan CP, et al. Systematic review of the impact of physician work schedules on patient safety with meta-analyses of mortality risk. *Jt Comm J Qual Patient Saf*. 2023;49(11):634-647.

[28] Miulli DE, Valcore JC. Methods and implications of limiting resident duty hours. *J Am Osteopath Assoc*. 2010;110(7):385-395.

work hours.[29] This in turn led to the formation of the Bell Commission, which in 1987 recommended limiting resident physician work hours to no more than 24 consecutive work hours and no more than 80 hours a week. In 1989 these recommendations were implemented in New York, which became the first state in the United States to regulate work hours for resident physicians. The recommendations were not implemented in other states.

At present, the ACGME, which became an independent corporation in 2002, is solely responsible for accrediting residency programs in the United States and for monitoring residency programs' compliance with its work-hour standards. However, as discussed in more detail below, the ACGME does not adequately enforce its work-hour standards, and violations are not always reported.[30]

In 2003 the ACGME first limited work hours for all resident physicians to a maximum of 80 to 88 hours a week (averaged over four weeks) and limited extended shifts to 24 continuous hours that could be extended to 30 hours "for continuity of care and education" (see Table 2 for additional details).[31] In 2009, however, the IOM concluded in an influential report that working more than 16 hours consecutively without sleep is unsafe.[32] In fact, the report stated that if no protected sleep period is provided, shifts "must not exceed 16 hours."

In part based on the results of the IOM report,[33] the ACGME put new work-hour regulations into effect in 2011.[34] The new standard kept the weekly limit at 80 to 88 hours for all resident physicians (averaged over four weeks, as per their 2003 work-hour policy) and required that extended shifts be capped at 16 hours for first-year resident physicians (interns) only (see Table 2).[35] The ACGME argued that limiting shifts to 16 hours for interns is warranted because "PGY-1 [postgraduate year one] residents make more errors when working longer consecutive hours." However, against the recommendations of the IOM report, many resident physicians (roughly 80% of resident physicians are in the second or later years of residency training) were permitted

[29] Philibert I, Taradejna C. A brief history of duty hours and resident education. In: Philibert I, Amis Jr S, Vasilou E. ACGME task force on quality care and professionalism: The ACGME 2011 duty hour standard. Enhancing Quality of Care, Supervision, and Resident Professional Development. Chicago, IL; 2011: 5-11.
[30] Landrigan CP, Barger LK, Cade BE, et al. Interns' compliance with accreditation council for graduate medical education work-hour limits. *JAMA.* 2006;296(9):1063-1070.
[31] Accreditation Council for Graduate Medical Education (ACGME). The ACGME's approach to limit resident duty hours 12 months after implementation: a summary of achievements. https://www.acgme.org/globalassets/pfassets/publicationspapers/dh_dutyhoursummary2003-04.pdf. Accessed April 25, 2025.
[32] Institute of Medicine. Committee on Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedule to Improve Patient Safety. Resident Duty Hours: Enhancing Sleep, Supervision, and Safety, National Research Council. Ulmer C, Miller Wolman D, Johns MME, editors. Washington (DC): The National Academies Press; 2009.
[33] Fletcher KE, Reed DA, Arora VM. Patient safety, resident education and resident well-being following implementation of the 2003 ACGME duty hour rules. *J Gen Intern Med*. 2011;26(8):907-919.
[34] Nasca TJ, Day SH, Amis ES Jr; ACGME Duty Hour Task Force. The new recommendations on duty hours from the ACGME Task Force. *N Engl J Med*. 2010;363(2):e3.
[35] Accreditation Council for Graduate Medical Education. The ACGME 2011 duty hour standards: enhancing quality of care, supervision, and resident professional development. 2011. https://www.acgme.org/globalassets/pdfs/jgme-monograph1.pdf. Accessed April 25, 2025.

to continue working continuously in shifts that could still be extended from 24 up to 28 hours (instead of 30 hours as per the 2003 standard).[36]

ACGME's reasoning for only limiting shifts to 16 hours for interns was in part that resident physicians in their second or later year of training had already gained more experience that could help them counterbalance the risks associated with extended shifts. However, there are no data suggesting that more experience makes people less vulnerable to the negative effects of sleep deprivation or that more training will help overcome the safety concerns associated with fatigue.[37,38] The ACGME further argued that work-hour regulations could lead to a shift-worker mentality that stands in opposition to the professional responsibilities physicians have towards their patients.[39] Moreover, the ACGME argued that reduced work hours would leave resident physicians unprepared for their duties after their residencies when they need to "function when fatigued."[40] Of note here is, however, that resident physicians usually work more hours a week and longer shifts than attending physicians, other health care workers, or workers in other professions.[41,42] As will be discussed in more detail below, evidence also shows that reducing work hours does not negatively affect the continuity of care for patients or learning opportunities for resident physicians.

The 2011 work-hour policies were in place until 2017, when the ACGME reversed its decision to limit shift length to 16 hours for interns and again permitted all resident physicians to work extended shifts of 24 hours with an additional four hours "for transitioning care and formal didactics," for a total of 80-88 hours per week (averaged over four weeks; see Table 2 for additional details).[43] This decision was in part based on the publication of the 2016 Flexibility in Duty Hour Requirements for Surgical Trainees (FIRST) trial,[44] which found that the surgical patient safety outcomes in residency programs with flexible, extended-duration shifts were non-inferior (meaning no worse) than in those with limited work hours. The ACGME also claimed that the results of the Individualized Comparative Effectiveness of Models Optimizing Patient

[36] Czeisler CA, Weaver MD, Landrigan CP, et al. Extended work hours increase risk of harm, regardless of resident physicians' experience levels. *BMJ*. 2023;381(April 13):838.
[37] *Ibid.*
[38] Barger LK, Weaver MD, Sullivan JP, et al. Impact of work schedules of senior resident physicians on patient and resident physician safety: nationwide, prospective cohort study. *BMJ Med.* 2023;2(1):e000320.
[39] Accreditation Council for Graduate Medical Education. The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development. 2011. https://www.acgme.org/globalassets/pdfs/jgme-monograph1.pdf. Accessed April 25, 2025.
[40] Nasca TJ, Day SH, Amis ES Jr; ACGME Duty Hour Task Force. The new recommendations on duty hours from the ACGME Task Force. *N Engl J Med*. 2010;363(2):e3.
[41] Maoz Breuer R, Waitzberg R, Breuer A, et al. Work like a doc: A comparison of regulations on residents' working hours in 14 high-income countries. *Health Policy.* 2023;130(April):104753.
[42] Weaver MD, Barger LK, Sullivan JP, et al. Public opinion of resident physician work hours in 2022. *Sleep Health.* 2024;10(1S):S194-S200.
[43] Burchiel KJ, Zetterman RK, Ludmerer KM, et al. The 2017 ACGME common work hour standards: promoting physician learning and professional development in a safe, humane environment. *J Grad Med Educ*. 2017;9(6):692-696.
[44] Bilimoria KY, Chung JW, Hedges LV, et al. National cluster-randomized trial of duty-hour flexibility in surgical training. *N Engl J Med*. 2016;374(8):713-727.

Safety and Resident Education (iCOMPARE) trial, published in 2019,[45] constituted additional support for the ACGME's reversal of the 2011 work-hour standards.[46] This trial again found that for several patient outcomes, including 30-day mortality, extended-duration shifts were non-interior to limited shifts. However, as discussed in more detail below, both trials were funded by the ACGME, poorly designed, and raised ethical concerns.[47]

Importantly, however, evidence from the two trials showed that extended shifts led to decreased well-being, morale, and health in resident physicians and that interns who were working longer shifts had to change their sleep patterns to compensate for extended shifts. At the same time, both trials showed that working long hours was non-inferior to working shorter hours not only for patient safety but also for educational outcomes.[48]

At present, the 2017 ACGME work-hour policies are still in place.[49] Not only do these standards fall short of the recommendations of several expert panels, but they are also not supported by the growing body of research that clearly demonstrates the detrimental effect of sleep deprivation associated with long work hours and extended shifts on the health and safety of resident physicians and the patients in their care. An overview of the key literature is provided below, which updates the evidence presented in the 2001[50] and 2010[51] petitions.

Moreover, the 2017 work standards provide even less protection for resident physicians than the ACGME's 2011 work-hour regulations did.[52] This rollback of ACGME's 2011 cap on shifts of more than 16 continuous hours for interns was based on trials that not only were poorly designed but also failed to demonstrate the necessity of extended shifts for patient safety or optimal educational outcomes.

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[45] Silber JH, Bellini LM, Shea JA, et al. Patient safety outcomes under flexible and standard resident duty-hour rules. *N Engl J Med*. 2019;380(10):905-914.

[46] Accreditation Council for Graduate Medical Education. ACGME statement about iCOMPARE study results. March 7, 2019. https://www.acgme.org/newsroom/2019/3/acgme-statement-about-icompare-study-results/. Accessed April 25, 2025.

[47] Public Citizen. Effort to weaken rules on resident physician work hours threatens safety of residents and their patients. March 15, 2016. https://www.citizen.org/news/effort-to-weaken-rules-on-resident-physician-work-hours-threatens-safety-of-residents-and-their-patients/. Accessed April 25, 2025.

[48] Weaver MD, Landrigan CP, Sullivan JP, et al. National improvements in resident physician-reported patient safety after limiting first-year resident physicians' extended duration work shifts: a pooled analysis of prospective cohort studies. *BMJ Qual Saf*. 2022;32(2):81-89.

[49] Accreditation Council for Graduate Medical Education. ACGME common program requirements (residency). September 17, 2022. https://www.acgme.org/globalassets/pfassets/programrequirements/cprresidency_2023.pdf. Accessed April 25, 2025.

[50] Public Citizen. Petition requesting medical residents work hour limits. April 30, 2001. https://www.citizen.org/article/petition-requesting-medical-residents-work-hour-limits/. Accessed April 25, 2025.

[51] Public Citizen. Petition to reduce medical resident work hours. September 2, 2010. https://www.citizen.org/article/petition-to-reduce-medical-resident-work-hours-2/. Accessed April 25, 2025.

[52] Accreditation Council for Graduate Medical Education. The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development. 2011. https://www.acgme.org/globalassets/pdfs/jgme-monograph1.pdf. Accessed April 25, 2025.

Table 2: Summary of Several Key ACGME Work-Hour Requirements in 2003, 2011, and 2017

	2003 ACGME Work-Hour Requirements[53]	**2011 ACGME Work-Hour Requirements**[54]	**2017 ACGME Work-Hour Requirements**[55]
Maximum hours of work per week	80 hours, up to 88 hours for some specialties (averaged over four weeks)	80 hours, up to 88 hours for some specialties (averaged over four weeks)	80 hours, up to 88 hours for some specialties (averaged over four weeks)
Maximum shift length	30 hours (24 hours plus 6 hours for "continuity of care and education")	16 hours for interns only 28 hours for all other resident physicians (24 hours plus 4 hours for "transitions in care")	Elimination of 16-hour cap for interns[56] 28 hours (24 hours plus 4 hours for "activities related to patient safety… and/or resident education")
Maximum in-hospital on-call frequency	Once every three nights (averaged over four weeks)	no more than every third night (averaged over four weeks) for second-year resident physicians and above	no more than every third night (averaged over four weeks)
Minimum time off between scheduled shifts	10 hours between duty periods	8-10 hours between duty periods 14 hours free of duty after 24 hours of in-house duty	Eight hours between scheduled clinical work and education periods 14 hours off clinical work and education after 24 hours of in-house call
Minimum time off duty	One day free per seven days (averaged over four weeks)	One day free every week (averaged over four weeks)	One day free of clinical work and required education per seven days (averaged over four weeks)

[53] Accreditation Council for Graduate Medical Education (ACGME). The ACGME's approach to limit resident duty hours 12 months after implementation: a summary of achievements. https://www.acgme.org/globalassets/pfassets/publicationspapers/dh_dutyhoursummary2003-04.pdf. Accessed April 25, 2025.

[54] Accreditation Council for Graduate Medical Education. The ACGME 2011 duty hour standards: enhancing quality of care, supervision, and resident professional development. 2011. https://www.acgme.org/globalassets/pdfs/jgme-monograph1.pdf. Accessed April 25, 2025.

[55] Accreditation Council for Graduate Medical Education. ACGME common program requirements (residency). September 17, 2022. https://www.acgme.org/globalassets/pfassets/programrequirements/cprresidency_2023.pdf. Accessed April 25, 2025.

[56] Burchiel KJ, Zetterman RK, Ludmerer KM, et al. The 2017 ACGME common work hour standards: promoting physician learning and professional development in a safe, humane environment. *J Grad Med Educ*. 2017;9(6):692-696.

1.2 CMS has jurisdiction over limiting resident physician work hours

At present, the federal government does not regulate resident physician work hours. This is particularly striking because there are federal work-hour regulations for employees in many other occupations, such as pilots and truck drivers.[57] The ACGME, an "independent, 501(c)(3), not-for-profit organization,"[58] accredits residency programs and is also responsible for regulating and enforcing work hours. As will be demonstrated in this petition, the ACGME has not adequately limited work hours to protect resident physicians and their patients. Moreover, as will be discussed in detail below, the ACGME has not robustly enforced its current work-hour standards and penalized work-hour violations when they occur. The dual role of the ACGME creates additional problems. For instance, resident physicians who report work-hour violations may in fact be penalized by their program or risk that their program will lose its ACGME accreditation if their concerns are fully addressed.

Establishing and enforcing federal evidence-based work-hour standards for resident physicians is essential to 1) ensure a humane and safe work environment for resident physicians and 2) decrease the risk that patients will be harmed by resident physicians with excessive work hours. The petitioners maintain that CMS has jurisdiction over establishing and enforcing a federal work-hour standard. Petitioners are not requesting that CMS assumes oversight of resident physician education and residency programs, which should be the continuing responsibility of the ACGME.

The mission of CMS is to "improve quality, equity and outcomes in the health care system."[59] Because CMS is both the main funder of residency programs and the largest payer for health care in the United States,[60] the petitioners maintain that CMS has a vested interest and responsibility to regulate work hours so that resident physicians have a safe and healthful work environment and that the care they provide is safe and effective.

In 2022 the National Health Expenditure (NHE) of the United States reached $4.5 trillion and accounted for 17.3% of gross domestic product.[61] Together, Medicare (21% of NHE) and Medicaid (18% of NHE) spending amounted to approximately $1.8 trillion. Moreover, CMS is

[57] Barger LK, Lockley SW, Rajaratnam SM, et al. Neurobehavioral, health, and safety consequences associated with shift work in safety-sensitive professions. *Curr Neurol Neurosci Rep*. 2009;9(2):155-164.
[58] The Accreditation Council for Graduate Medical Education. About the ACGME. https://www.acgme.org/about/overview/. Accessed April 25, 2025.
[59] Centers for Medicare and Medicaid Services. About us. https://www.cms.gov/about-cms. Accessed April 25, 2025.
[60] Centers for Medicare and Medicaid Services. CMS roadmaps overview. https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/qualityinitiativesgeninfo/downloads/roadmapoverview_oea_1-16.pdf. Accessed April 25, 2025.
[61] Centers for Medicare and Medicaid Services. NHE fact sheet. September 10, 2024. https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet. Accessed April 25, 2025.

responsible for providing health coverage to more than 160 million Americans, including beneficiaries of Medicare and Medicaid.[62]

Teaching hospitals provide most of the hospital care for Medicare beneficiaries, and resident physicians provide a large proportion of the direct care in these institutions.[63,64] Since the Medicare program began in 1965, graduate medical education in teaching hospitals has been paid in large part through Medicare.[65,66] In 2020, for example, CMS paid about $16 billion to residency programs.

CMS's financial support of residency programs thus makes it the main funder of a large proportion of resident physicians. About 14% of all physicians in the United States are resident physicians, including fellows.[67] In the 2023-2024 academic year, there were more than 162,000 full- and part-time resident physicians and fellows in ACGME-accredited residency programs.

Providers in Medicare and Medicaid programs must meet health and safety standards that are established under the Social Security Act.[68] Specifically, under 42 C.F.R. § 481.1,[69] "(i) [h]ospitals participating in Medicare must meet certain specified requirements; and (ii) [t]he Secretary may impose additional requirements if they are found necessary in the interest of the health and safety of the individuals who are furnished services in hospitals." The secretary of the Department of Health and Human Services (HHS) has designated CMS as the HHS agency responsible for ensuring that the Medicare and Medicaid programs comply with the established standards. The petitioners therefore request that the administrator of the Centers for Medicare and Medicaid Services exercise this authority on the grounds that work hours in excess of the requested work-hour limits may lead to worse patient safety outcomes, if patients are cared for by sleep deprived and fatigued resident physicians.

[62] Centers for Medicare and Medicaid Services. About us. https://www.cms.gov/about-cms. Accessed April 25, 2025.
[63] Weaver MD, Barger LK, Sullivan JP, et al. Public opinion of resident physician work hours in 2022. *Sleep Health*. 2024;10(1S):S194-S200.
[64] Association of American Medical Colleges. Analysis in brief. Hospital transfers of Medicare patients. February 2009. https://www.aamc.org/media/9996/download. Accessed April 25, 2025.
[65] DeMarco DM, Forster R, Gakis T, et al. Eliminating residents increases the cost of care. *J Grad Med Educ*. 2017;9(4):514- 517.
[66] Congressional Research Service. Medicare graduate medical education payments: An overview. September 29, 2022. https://crsreports.congress.gov/product/pdf/IF/IF10960. Accessed April 25, 2025.
[67] Accreditation Council for Graduate Medical Education. About us: ACGME by the numbers. https://www.acgme.org/about-us/overview. Accessed April 25, 2025.
[68] Centers for Medicare and Medicaid Services. Quality, safety & oversight – regulations, certification & compliance. November 14, 2024. https://www.cms.gov/medicare/health-safety-standards/certification-compliance. Accessed April 25, 2025.
[69] 42 C.F.R. § 482.1.

Part 2: Arguments for Reducing Work Hours, Evidence of Harm to Resident Physicians

There is extensive evidence that sleep loss due to long work hours and extended shifts has a profound influence on resident physician health, safety, and well-being.[70] For instance, sleep deprivation has been linked to unwanted weight changes, increased use of medication, and increased alcohol consumption.[71] Impaired sleep is also associated with reduced cognitive performance, which can affect resident physicians' ability to retain knowledge and their ability to learn.[72,73]

Moreover, numerous studies have demonstrated that sleep deprivation among resident physicians is associated with decreased alertness and vigilance. For instance, one study found that when resident physicians worked more than 48 hours a week, they were significantly more likely to report motor vehicle crashes and near-miss crashes, needlestick injuries, and other occupational exposures to potentially contaminated body fluids.[74] When resident physicians worked more than one extended-duration shift a month, these risks increased substantially. The long work hours associated with residency have also been linked to obstetric complications in pregnant resident physicians.[75] Lack of sleep has been shown to affect mental health (such as depression and burnout), with consequences for resident physicians' well-being and the patients in their care.[76]

Reducing work hours for resident physicians can be an effective tool to mitigate these risks. For instance, a 2020 prospective analysis found that the work-hour limits mandated by the ACGME in 2011 helped to reduce the risk of motor vehicle crashes by 24% and reduced the number of near crashes by 44%.[77] Among interns, the risk of needlestick injuries decreased by 46%. Moreover, a 2006 survey across different specialties in one university found that 77% of interns were burnt out before the 2003 ACGME work-hour standard, whereas significantly fewer interns (43%) reported burnout after their implementation.[78]

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[70] Hanna J, Gutteridge D, Kudithipudi V. Finding the elusive balance between reducing fatigue and enhancing education: perspectives from American residents. *BMC Med Educ*. 2014;14(Suppl 1):S11.

[71] Baldwin DC Jr, Daugherty SR. Sleep deprivation and fatigue in residency training: results of a national survey of first- and second-year residents. *Sleep.* 2004;27(2):217-223.

[72] Philibert I. Sleep loss and performance in residents and nonphysicians: A meta-analytic examination. *Sleep.* 2005;28(11):1392-1402.

[73] Papp KK, Stoller EP, Sage P, et al. The effects of sleep loss and fatigue on resident-physicians: a multi-institutional, mixed-method study. *Acad Med.* 2004;79(5):394-406.

[74] Barger LK, Weaver MD, Sullivan JP, et al. Impact of work schedules of senior resident physicians on patient and resident physician safety: nationwide, prospective cohort study. *BMJ Med.* 2023;2(1):e000320.

[75] Li RD, Janczewski LM, Eng JS, et al. Pregnancy and parenthood among US surgical residents. *JAMA Surg.* 2024.159(10):1127-1137.

[76] Martini S, Arfken CL, Balon R. Comparison of burnout among medical residents before and after the implementation of work hours limits. *Acad Psychiatry*. 2006;30(4):352-355.

[77] Weaver MD, Landrigan CP, Sullivan JP, et al. The association between resident physician work-hour regulations and physician safety and health. *Am J Med.* 2020;133(7):e343-e354.

[78] Martini S, Arfken CL, Balon R. Comparison of burnout among medical residents before and after the implementation of work hours limits. *Acad Psychiatry*. 2006;30(4):352-355.

2.1. Evidence of sleep deprivation in resident physicians

Research has repeatedly shown that for employees in safety-sensitive professions (such as firefighters, police officers, pilots, first responders, and health care providers), shift work (night shifts, extended-duration shifts, and rotating shifts [referring to shifts that are scheduled to change regularly]) can lead to acute or chronic sleep deprivation and circadian desynchronization.[79] This can in turn increase the risk of short- and long-term health problems, such as gastric and duodenal ulcers, cardiovascular disease, obesity, and cancer. In 2024 a Government Accountability Office report recognized "very long work hours," defined as 55 work hours or more per week, as a risk factor for stroke and heart disease.[80]

It is also well documented that sleep deprivation can take a toll on stress-management abilities and negatively affects interpersonal skills and mood. For instance, sleep-deprived individuals tend to have lower empathy towards others and a decreased ability to accurately recognize human emotions.[81,82] Inadequate sleep has also been associated with decreased alertness, deteriorating performance, and a decreased ability to concentrate, which has important implications for safety.[83] Sleep deprivation in safety-sensitive occupations can thus profoundly affect public safety.

Resident physicians are at a particularly high risk of sleep deprivation because they frequently are required to work long hours, often with little opportunity to sleep during extended shifts. There is extensive evidence that for resident physicians across specialties, sleep loss associated with shifts of more than 16 consecutive hours has numerous detrimental effects, both for their own well-being and for the safety of the patients in their care (as discussed in Part 3 below).[84,85] Moreover, because the loss of sleep is cumulative over the course of residency, resident physicians frequently suffer both from acute sleep loss and chronic sleep deprivation.

A national survey on self-reported sleep hours among approximately 3,600 interns and second-year resident physicians across several specialties in the 1998-1999 training year, published in 2004, showed that those who had slept for an average of five or fewer hours per night were more likely to report negative outcomes of sleep deprivation.[86] Similarly, an anonymous internet-based

[79] Barger LK, Lockley SW, Rajaratnam SM, et al. Neurobehavioral, health, and safety consequences associated with shift work in safety-sensitive professions. *Curr Neurol Neurosci Rep*. 2009;9(2):155-164.
[80] Government Accountability Office. Work hours and health. September 11, 2024. https://www.gao.gov/assets/gao-24-106772.pdf. Accessed April 25, 2025.
[81] van der Helm E, Gujar N, Walker MP. Sleep deprivation impairs the accurate recognition of human emotions. *Sleep.* 2010;33(3):335-342.
[82] Killgore WD, Kahn-Greene ET, Lipizzi EL, et al. Sleep deprivation reduces perceived emotional intelligence and constructive thinking skills. *Sleep Med.* 2008;9(5):517-526.
[83] Barger LK, Lockley SW, Rajaratnam SM, et al. Neurobehavioral, health, and safety consequences associated with shift work in safety-sensitive professions. *Curr Neurol Neurosci Rep.* 2009;9(2):155-164.
[84] Philibert I. Sleep loss and performance in residents and nonphysicians: A meta-analytic examination. *Sleep.* 2005;28(11):1392-1402.
[85] St Hilaire MA, Anderson C, Anwar J, et al. Brief (< 4 hr) sleep episodes are insufficient for restoring performance in first-year resident physicians working overnight extended-duration work shifts. *Sleep.* 2019;42(5):zsz041.
[86] Baldwin DC Jr, Daugherty SR. Sleep deprivation and fatigue in residency training: results of a national survey of first- and second-year residents. *Sleep.* 2004;27(2):217-223.

survey among 178 otolaryngology resident physicians published in 2016 found that those who slept less than six hours a night or worked more than 60 hours a week were significantly sleepier and more fatigued than those who slept more than six hours a night.[87] In fact, many resident physicians stated that they were excessively (32%) or severely (12%) sleepy, and the majority (78%) reported that their sleep had an effect on their daily functioning.

Another study, published in 2017, assessed the alertness of first-year resident physicians during their internal medicine and oncology rotations.[88] Interns who worked extended overnight shifts (often sleeping only about two hours or less) were compared with those who rarely or never worked long overnight shifts. Interns who were on call during nights slept on average 2.2 hours and during 18% of nights did not sleep at all. Not only did the interns report that they were "profoundly impaired," but compared with those on regular shifts, they were significantly less alert in the morning after a night on call.

"Strategic napping" during extended shifts has sometimes been suggested to help mitigate some of the detrimental effects of sleep loss. However, research does not support a role for strategic napping in mitigating sleep loss, possibly due to the underlying levels of acute and chronic sleep loss.[89,90] For example, a study including 34 first-year resident physicians published in 2019 found that on 92% of nights in which resident physicians worked extended shifts, they had less than four hours of sleep.[91] Importantly, with less than four hours of sleep, they had more attentional failures than when they were scheduled to work without extended shifts. The researchers found that significant reductions in attentional failures occurred only if resident physicians slept more than four hours during their extended shift, but they still had nearly three times the levels of attentional failures during post-call compared with post-call during work schedules without extended work hours.

Resident physicians tend to not be able to objectively rate their own sleepiness or may think that they can acclimate to sleep deprivation. They may continue to feel that they are able to function, learn, or care for patients despite being severely fatigued.[92, 93]

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[87] Nida AM, Googe BJ, Lewis AF, et al. Resident fatigue in otolaryngology residents: a Web based survey. *Am J Otolaryngol.* 2016;37(3):210-216.

[88] Basner M, Dinges DF, Shea JA, et al. Sleep and alertness in medical interns and residents: an observational study on the role of extended shifts. *Sleep*. 2017;40(4):zsx027.

[89] Nida AM, Googe BJ, Lewis AF, et al. Resident fatigue in otolaryngology residents: a Web based survey. *Am J Otolaryngol.* 2016;37(3):210-216.

[90] St Hilaire MA, Anderson C, Anwar J, et al. Brief (< 4 hr) sleep episodes are insufficient for restoring performance in first-year resident physicians working overnight extended-duration work shifts. *Sleep.* 2019;42(5):zsz041.

[91] *Ibid.*

[92] Olson EJ, Drage LA, Auger RR. Sleep deprivation, physician performance, and patient safety. *Chest.* 2009;136(5):1389-1396.

[93] Arnedt JT, Owens J, Crouch M, et al. Neurobehavioral performance of residents after heavy night call vs after alcohol ingestion. *JAMA.* 2005;294(9):1025-1033.

2.2. Increased risk of motor vehicle crashes

According to the Bureau of Transportation Statistics there were 5,250,837 motor vehicle crashes in the United States in 2020, leading to 2,282,015 injured persons and 38,824 fatalities.[94] One contributing factor is drowsy driving. One analysis, for example, identified operator fatigue (which is associated with a decreased ability to concentrate, and can affect reaction times, alertness, and cognitive function) as a probable cause or finding in 40% of highway-crash investigations.[95]

Between 2000 and 2014 motor vehicle accidents were one of the leading causes of mortality among U.S. resident physicians.[96] Surveys, studies, and driving simulations among resident physicians from numerous specialties demonstrate that driving while sleep deprived, fatigued, or driving after a night shift or a shift of more than 16 consecutive hours puts resident physicians at significant risk of traffic safety events (such as falling asleep while driving, stopping in traffic, near-miss crashes, and motor vehicle crashes).[97,98 ,99]

A survey published in 1996 compared 70 pediatric resident physicians who were on call every fourth night with 85 faculty members, who were rarely disturbed at night.[100] 44% of pediatric resident physicians who slept little while on call (average 2.7 hours) fell asleep at the wheel while stopping at a red light (mainly while driving post-call) compared with 12.5% of faculty who had slept for an average of 6.5 hours.

A national survey published in 2004 on self-reported sleep hours among 3,604 interns and second-year resident physicians across several specialties reported similar outcomes.[101] Resident physicians who had slept five or fewer hours per night were more likely to report negative outcomes of sleep deprivation, including being 1.8 times more likely to be involved in a serious accident or injury, than those who had slept longer. They were also 1.7 times more likely to report making a significant medical error.

A 2005 web-based prospective survey based on 17,003 monthly reports of 2,737 first-year resident physicians found that in the months in which interns worked five or more extended shifts (24 hours or more), their risk of falling asleep while driving or while stopped in traffic was

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[94] Bureau of Transportation Statistics. Motor vehicle safety data. https://www.bts.gov/content/motor-vehicle-safety-data. Accessed April 25, 2025.

[95] Marcus JH, Rosekind MR. Fatigue in transportation: NTSB investigations and safety recommendations. *Inj Prev.* 2017;23(4):232-238.

[96] Yaghmour NA, Brigham TP, Richter T, et al. Causes of death of residents in ACGME-accredited programs 2000 through 2014: Implications for the learning environment. *Acad Med*. 2017;92(7):976-983.

[97] Nida AM, Googe BJ, Lewis AF, et al. Resident fatigue in otolaryngology residents: a Web based survey. *Am J Otolaryngol.* 2016;37(3):210-216.

[98] West CP, Tan AD, Shanafelt TD. Association of resident fatigue and distress with occupational blood and body fluid exposures and motor vehicle incidents. *Mayo Clin Proc.* 2012;87(12):1138-1144.

[99] Ware JC, Risser MR, Manser T, et al. Medical resident driving simulator performance following a night on call. *Behav Sleep Med*. 2006;4(1):1-12.

[100] Marcus CL, Loughlin GM. Effect of sleep deprivation on driving safety in housestaff. *Sleep*. 1996;19(10):763-766.

[101] Baldwin DC Jr, Daugherty SR. Sleep deprivation and fatigue in residency training: results of a national survey of first- and second-year residents. *Sleep*. 2004;27(2):217-223.

significantly increased.[102] In addition, the monthly risk of a motor vehicle crash during the commute from work increased by 16.2 % for every scheduled extended work shift. Moreover, resident physicians were more than twice as likely to have a documented motor vehicle crash on their commute after an extended shift. Near-miss incidents were also more than five times as likely after an extended shift than a standard one.

Another study, also published in 2005, demonstrated that long work hours and limited sleep impaired the psychomotor performance of resident physicians to a similar degree as having about three to four standard drinks (0.04 to 0.05 g% blood alcohol concentration) during a light call rotation.[103] This finding is of particular concern because alcohol ingestion is an accepted standard for functional impairment and is well known to decrease inhibitions and diminish attention and judgment, which can thus lead to hazardous driving. In this study, the post-call performance on several tests (including for sustained attention and simulated driving) of 34 pediatric resident physicians in the final week of a four-week rotation with heavy call duty (working on average between 80 to 90 hours a week and working consecutive shifts of 34-36 hours every fourth or fifth night) was equivalent to or worse than that of resident physicians with light call rotations (working with some exceptions only daytime shifts for an average of 44 hours per week) who had a 0.04 to 0.05 g% blood alcohol concentration. Resident physicians on heavy call duty also had slower reaction times, were less alert, and made more commission and omission errors. They were also significantly less likely to stay in their lane and maintain speed during simulated driving tests.

In a 2016 study, 29 anesthesiology resident physicians had a driving simulator test after six consecutive overnight work shifts.[104] The study found that the resident physicians had significantly impaired driving performance compared with when they took the test at the beginning of a day shift (that was not after a shift on call), including slower reaction times, an increase in the number of lapses in attention, and difficulties with lane position, steering, and controlling speed. For example, after six night shifts, resident physicians had an increased number of collisions compared with after a day shift. After six overnight work shifts, resident physicians also reported feeling less safe to drive and felt significantly sleepier and less alert than after a day shift.

A 2018 study used specialized glasses and a drowsiness measurement system to assess the drowsiness levels of 16 resident physicians from different specialties on their work commutes.[105] The study found that after a shift of 24 hours or more, resident physicians were sleepier on their commute from work (75%) than their commute to work (12%). Extended work hours were also associated with an increase of about 40% in self-reported sleepiness on the commute home and were positively correlated with objective measurements of drowsiness. Unsurprisingly, on the

[102] Barger LK, Cade BE, Ayas NT, et al. Extended work shifts and the risk of motor vehicle crashes among interns. *N Engl J Med*. 2005;352(2):125-134.
[103] Arnedt JT, Owens J, Crouch M, et al. Neurobehavioral performance of residents after heavy night call vs after alcohol ingestion. *JAMA.* 2005;294(9):1025-1033.
[104] Huffmyer JL, Moncrief M, Tashjian JA, et al. Driving performance of residents after six consecutive overnight work shifts. *Anesthesiology.* 2016, 124(6):1396-1403.
[105] Anderson C, Ftouni S, Ronda JM, et al. Self-reported drowsiness and safety outcomes while driving after an extended duration work shift in trainee physicians. *Sleep.* 2018;41(2):zsx195.

commute home after extended shifts, resident physicians had three to five times greater odds of reporting sleep-related inattentive or hazardous driving than when commuting to work.

A 2021 retrospective survey among 58 general surgery resident physicians found that 96.6% of resident physicians who commuted for work reported work-related fatigue that diminished their ability to drive safely and 82.8% reported that they had fallen asleep or almost fell asleep while driving on their commute to or from work.[106] Close to two-thirds of resident physicians reported that fatigue was an issue for their driving safety on a daily or weekly basis. Most resident physicians (75.9%) reported feeling the greatest fatigue after a scheduled 24-hour shift.

A national survey among over 7,300 general surgery resident physicians published in 2021 found that self-reported hazardous traffic-safety events were more common among those who worked more hours than the ACGME work-hour standard than those with fewer work-hour violations.[107] For instance, those who had frequently violated the 80-hours-per-week limit over the past six months reported nodding off (59.8%), having near-miss motor vehicle crashes (53.6%), and motor vehicle crashes (14.0%) more often than those without such violations (27.2%, 19.2%, and 3.5%, respectively). Similarly, 50.8% of those who reported that they had eight or fewer hours off work between shifts three or more times in the most recent month reported nodding off and 11.7% reported motor vehicle crashes, in contrast with 32.8% and 4.2%, respectively, of resident physicians who reported having eight or fewer hours off work between shifts two or fewer times.

In 2023 a nationwide, prospective cohort study found that resident physicians in their second or higher year of training had more than double the risk of near-miss motor vehicle crashes when they worked more than 70 hours a week than did resident physicians who had worked no more than 48 hours a week.[108] Those who worked longer hours also had a significantly higher risk of near-miss crashes when they worked one or more extended shifts (while averaging no more than 80 hours per week in a month). The resident physicians who worked extended shifts and worked more than 80 hours a week had the highest risk.

2.3. Increased risk of percutaneous injuries

According to the Centers for Disease Control and Prevention, percutaneous injuries (also called needlestick injuries) are sharps injuries involving "a penetrating stab wound from a needle, scalpel, or other sharp object that may result in exposure to blood or other body fluids."[109] Although needlestick injuries are often not reported, they are a serious health concern and are among the most common occupational hazards for health care workers.[110] For example, each

[106] Freedman-Weiss MR, Heller DR, White EM, et al. Driving safety among surgical residents in the era of duty hour restrictions. *J Surg Educ*. 2021;78(3):770-776.
[107] Schlick CJ, Hewitt DB, Quinn CM, et al. A national survey of motor vehicle crashes among general surgery residents. *Ann Surg*. 2021;274(6):1001-1008.
[108] Barger LK, Weaver MD, Sullivan JP, et al. Impact of work schedules of senior resident physicians on patient and resident physician safety: nationwide, prospective cohort study. *BMJ Med.* 2023;2(1):e000320.
[109] Centers for Disease Control and Prevention. Stop sticks campaign. Sharps injuries. February 26, 2019. https://archive.cdc.gov/#/details?url=https://www.cdc.gov/nora/councils/hcsa/stopsticks/sharpsinjuries.html. Accessed April 25, 2025.
[110] Borna R, Rahimian R, Koons BSN, et al. Needlestick injuries among anesthesia providers from a large US academic center: A 10-year retrospective analysis. *J Clin Anesth*. 2022;80(September):110885.

year there are about 385,000 percutaneous injuries among hospital-based health care workers[111] and, by some estimates, these injuries happen in about 15% of all operations.[112]

Although the risk of contracting an infectious disease through a needlestick injury is low,[113] these injuries can put health care personnel at risk of contracting hepatitis B, hepatitis C, human immunodeficiency virus (HIV), and several other blood-borne pathogens. Moreover, many blood-borne pathogens are not detected in patients prior to surgery. In fact, one study in an urban, university-based general surgical practice found that when blood was tested prior to surgeries, in 38% of cases, positive results for hepatitis B, hepatitis C, or HIV were found.[114] Needlestick injuries also put affected health care workers at risk of adverse effects from postexposure treatments to prevent or treat infections, can have implications for future employment, and are associated with substantial financial and psychosocial burdens.[115,116]

Needlestick injuries are also common among resident physicians,[117,118] who often have a higher risk of injuries than other health care professionals, including surgeons, medical students, or nurses. Evidence suggests that key contributors to the higher rates of these injuries among resident physicians are the long work hours, fatigue, and sleep deprivation associated with residency training.[119] For instance, a nationwide, prospective cohort study published in 2023 found a significant increase in self-reported needlestick injuries when work hours increased beyond 48 hours a week, such as when resident physicians worked one or more extended-duration shifts in a month.[120] By the end of their surgery residency training, most resident physicians had experienced at least one needlestick injury, many involving patients at high risk of harboring blood-borne pathogens.

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[111] Centers for Disease Control and Prevention. Sharps safety program resources. April 3, 2024. https://www.cdc.gov/sharpssafety/index.html. Accessed April 25, 2025.

[112] Sethi N, Evans D, Murray A. Needlestick occurrences and reporting among residents in the operative setting. *J Surg Educ.* 2020;77(6):1542-1551.

[113] Brasel KJ, Mol C, Kolker A, et al. Needlesticks and surgical residents: who is most at risk? *J Surg Educ.* 2007;64(6):395-398.

[114] Weiss ES, Makary MA, Wang T, et al. Prevalence of blood-borne pathogens in an urban, university-based general surgical practice. *Ann Surg.* 2005;241(5):803-807.

[115] Centers for Disease Control and Prevention. Stop sticks campaign. Sharps injuries. February 26, 2019. https://archive.cdc.gov/#/details?url=https://www.cdc.gov/nora/councils/hcsa/stopsticks/sharpsinjuries.html. Accessed April 25, 2025.

[116] Makary MA, Al-Attar A, Holzmueller CG, et al. Needlestick injuries among surgeons in training. *N Engl J Med.* 2007;356(26):2693-2699.

[117] Snavely JE, Service BC, Miller D, et al. Needlestick and sharps injuries in orthopedic surgery residents and fellows. *Infect Control Hosp Epidemiol.* 2019;40(11):1253-1257.

[118] Borna R, Rahimian R, Koons BSN, et al. Needlestick injuries among anesthesia providers from a large US academic center: A 10-year retrospective analysis. *J Clin Anesth*. 2022;80(September):110885.

[119] Fisman DN, Harris AD, Rubin M, et al. Fatigue increases the risk of injury from sharp devices in medical trainees results from a case-crossover study. *Infect Control Hosp Epidemiol.* 2007;28(1):10-17.

[120] Barger LK, Weaver MD, Sullivan JP, et al. Impact of work schedules of senior resident physicians on patient and resident physician safety: nationwide, prospective cohort study. *BMJ Med.* 2023;2(1):e000320.

Some studies indicate that more needlestick injuries are reported in the first years of residency training, particularly in the first six months[121] (arguably due to lack of experience).[122,123] Other studies indicate that the risk increases with the years in medical training.[124,125,126,127] In the later years of their training, resident physicians may spend more time in operating rooms and have more exposure to sharp instruments, despite being more familiar with medical and surgical procedures. For all resident physicians regardless of their level of experience, high workload, long work hours, fatigue, and stress have consistently been shown to contribute to their risk of sustaining a needlestick injury.

For example, a 2006 web-based prospective cohort study found that needlestick injuries were twice as frequent at night and that resident physicians had a 61% increase in the odds of such injuries when they worked 24 hours or more continuously.[128] For injuries that occurred at night or after extended shifts, resident physicians were significantly more likely to identify fatigue as a contributing factor. Another study published in 2007 found that fatigue associated with sleep deprivation and long work hours was associated with a threefold increase in the risk of needlestick injuries among resident physicians.[129] Resident physicians slept less than usual in the week before the injury, and reports of these injuries were also more likely if they were fatigued. Study participants were eight times as likely to report being fatigued at the time of the injury if they had been working for more than 12 hours and four times as likely if they had worked more than 40 hours or more than five days in the week prior to the injury.

A survey including all general surgery resident programs, published in 2019, found that surgical resident physicians who reported frequently working more than 80 hours per week had 42% higher odds of needlestick injuries.[130] Although the authors stated that "[t]he easiest explanation for this association is resident fatigue," the resident physicians themselves did not cite fatigue (21.4%) as the most common contributing factor but instead blamed their own carelessness (48.8%) or feeling rushed (31.3%). In another study, published in 2020, that included resident physicians from anesthesiology and several surgical specialties, fatigue was similarly not

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[121] Marnejon T, Gemmel D, Mulhern K. Patterns of needlestick and sharps injuries among training residents. *JAMA Intern Med.* 2016;176(2):251-252.

[122] Brasel KJ, Mol C, Kolker A, et al. Needlesticks and surgical residents: who is most at risk? *J Surg Educ.* 2007;64(6):395-398.

[123] Ayas NT, Barger LK, Cade BE, et al. Extended work duration and the risk of self-reported percutaneous injuries in interns. *JAMA*. 2006;296(9):1055-1062.

[124] Makary MA, Al-Attar A, Holzmueller CG, et al. Needlestick injuries among surgeons in training. *N Engl J Med*. 2007;356(26):2693-2699.

[125] Yang AD, Quinn CM, Hewitt DB, et al. National evaluation of needlestick events and reporting among surgical residents. *J Am Coll Surg*. 2019;229(6):609-620.

[126] Gordon AM, Hudson PW, Bowman JR, et al. Workplace hazards in orthopaedic surgery training: a nationwide resident survey involving sharps-related injuries. *J Am Acad Orthop Surg*. 2022;30(9):428-436.

[127] Borna R, Rahimian R, Koons BSN, et al. Needlestick injuries among anesthesia providers from a large US academic center: A 10-year retrospective analysis. *J Clin Anesth*. 2022;80(September):110885.

[128] Ayas NT, Barger LK, Cade BE, et al. Extended work duration and the risk of self-reported percutaneous injuries in interns. *JAMA*. 2006;296(9):1055-1062.

[129] Fisman DN, Harris AD, Rubin M, et al. Fatigue increases the risk of injury from sharp devices in medical trainees results from a case-crossover study. *Infect Control Hosp Epidemiol.* 2007;28(1):10-17.

[130] Yang AD, Quinn CM, Hewitt DB, et al. National evaluation of needlestick events and reporting among surgical residents. *J Am Coll Surg*. 2019;229(6):609-620.

identified by most as a contributing factor leading to needlestick injuries except by those in the only program that had received prior training on fatigue.[131] These findings may indicate that resident physicians who have not received prior training may not be able to accurately self-assess their levels of fatigue.

2.4. Increased risk of obstetric complications

Most women in medicine, including resident physicians, delay childbearing due to medical training or their career.[132] Delayed childbearing can have long-term health and financial consequences; in fact, fertility in women overall decreases by about 50% between their early twenties and late thirties.[133] Of more concern, however, is that if resident physicians are pregnant during their training, the long work hours associated with residency may increase their risk of poor obstetric outcomes.

Research has repeatedly demonstrated that in the general population, long work hours and night or rotating shifts can increase the risk of adverse pregnancy outcomes.[134] For example, standing or working for more than 30 hours a week has been linked to increased risks of preterm delivery,[135] miscarriage, or having an infant with low birth weight.[136] Similarly, rotating shifts have been weakly associated with increased odds for preeclampsia and gestational hypertension. Some research also indicates that sleep disturbances (including short or long sleep duration and poor sleep quality) may increase the risk of preeclampsia, gestational hypertension, and preterm birth.[137]

Given these increased risks of long work hours during pregnancy, it is not surprising that pregnant resident physicians are also at risk of adverse pregnancy outcomes, especially if they are working long hours, extended shifts, and experience sleep disturbances during residency training. For example, one survey of plastic-surgery resident physicians concluded that pregnant physicians had higher rates of several pregnancy complications than the general population, including miscarriages and hyperemesis gravidarum.[138] A systematic review of 27 studies published in 2020 found that pregnant surgical resident physicians had rates of pregnancy complications ranging from 25% to 82%, especially when they were working long hours or night

[131] Sethi N, Evans D, Murray A. Needlestick occurrences and reporting among residents in the operative setting. *J Surg Educ.* 2020;77(6):1542-1551.
[132] Bakkensen JB, Smith KS, Cheung EO, et al. Childbearing, infertility, and career trajectories among women in medicine. *JAMA Netw Open*. 2023;6(7):e2326192.
[133] Bourne DA, Chen W, Schilling BK, et al. The impact of plastic surgery training on family planning and prenatal health. *Plast Reconstr Surg*. 2019;144(5):1227-1236.
[134] Cai C, Vandermeer B, Khurana R, et al. The impact of occupational shift work and working hours during pregnancy on health outcomes: a systematic review and meta-analysis. *Am J Obstet Gynecol*. 2019;221(6):563-576.
[135] Vrijkotte T, Brand T, Bonsel G. First trimester employment, working conditions and preterm birth: a prospective population-based cohort study. *Occup Environ Med*. 2021;78(9):654-660.
[136] Vrijkotte TG, Van Der Wal MF, Van Eijsden M, et al. First-trimester working conditions and birthweight: a prospective cohort study. *Am J Public Health*. 2009;99(8):1409-1416.
[137] Lu Q, Zhang X, Wang Y, et al. Sleep disturbances during pregnancy and adverse maternal and fetal outcomes: A systematic review and meta-analysis. *Sleep Med Rev*.2021;58 (August):101436.
[138] Bourne DA, Chen W, Schilling BK, et al. The impact of plastic surgery training on family planning and prenatal health. *Plast Reconstr Surg*. 2019;144(5):1227-1236.

shifts.[139] These complication rates are much higher than for the general population (range of 5% to 15%).

In 2015 a retrospective cohort study of medical and surgical residency programs found that when pregnant resident physicians were on call during their pregnancy, they had a higher rate of complications than women of similar age in the general population.[140] Pregnant resident physicians had higher rates of miscarriage (11.8% vs. 4.2%), intrauterine growth restriction (9.2% vs. 3.9%), pregnancy-related hypertension (10.5% vs. 6.3%), and placental abruption (1.3% vs. 0%). For pregnant resident physicians who were on call for more than six nights per month, the overall rate of any of these risks was even higher (49.3%) compared with pregnant resident physicians who were on call for six or fewer nights per month (26.4%).

Several studies have found that pregnant resident physicians have higher rates of obstetric complications than the pregnant partners of male resident physicians. For example, a study published in 2003 showed that resident physicians who were pregnant during residency had a higher incidence of preeclampsia, fetal growth restrictions, and premature labor than the pregnant partners of male resident physicians.[141] A 2024 cross-sectional survey of 5,692 resident physicians in general surgery residency programs reported similar findings.[142] A significantly higher proportion of pregnant resident physicians experienced obstetric complications (41.8%) and postpartum depression (19.4%), than the pregnant partners of male resident physicians (33.7% and 12.5%, respectively). Postpartum depression can negatively affect the health of the child and is also associated with burnout and suicidal ideation.

Maternity leave and other current protections for pregnant resident physicians are not enough to address the increased risk of obstetric complications. For instance, the 2003 study found that pregnant resident physicians were more likely to work more than 80 hours a week than male resident physicians with pregnant partners, and they also seemed to increase their work hours, particularly during the first two trimesters of pregnancy.[143] More than three-quarters also took no days off work before delivery. Moreover, the 2020 systematic review that included studies published between the years 2003 and 2018 found that less than 12% of pregnant surgical resident physicians were working reduced hours and that 95% continued working night call shifts during their pregnancies.[144]

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[139] Todd AR, Cawthorn TR, Temple-Oberle C. Pregnancy and parenthood remain challenging during surgical residency: A systematic review. *Acad Med*. 2020;95(10):1607-1615.

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[144] Todd AR, Cawthorn TR, Temple-Oberle C. Pregnancy and parenthood remain challenging during surgical residency: a systematic review. *Acad Med*. 2020;95(10):1607-1615.

2.5. Increased risk of mental health conditions

Mental health conditions such as depression and burnout are common among all health workers and occur at a higher rate than would be expected in the general population.[145,146] In 2022 Dr. Vivek Murthy, then U.S. surgeon general, described burnout among health workers as a crisis and national priority that required change in "training institutions, where the seeds of wellbeing can be planted early."[147] Although burnout is not considered to be a medical condition, it "is a syndrome conceptualized as resulting from chronic workplace stress that has not been successfully managed" and is characterized by feeling exhausted, feeling negative or cynical about one's job, and being less effective.[148] Burnout is also associated with an increased risk of developing other mental health conditions and is a risk factor for substance abuse and depression.[149,150] Burnout is also associated with suicidal ideation, which is of particular concern because suicide is the second-leading cause of death among all resident physicians and the leading cause of death among male resident physicians.[151] Poor mental health during residency training can also have long-lasting consequences for resident physicians, including unintended weight changes[152] and an increased risk of future depressive episodes.[153] Resident physicians with poor mental health are also more likely to experience needlestick injuries.[154]

Research suggests that the rates of burnout and depression are especially high among resident physicians across all specialties[155,156] and that the risk of these conditions may be even higher for those in surgical residencies.[157] For example, a prospective cohort study among 123 pediatric resident physicians published in 2008 found that 20% of the resident physicians were at high risk

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[146] Fahrenkopf AM, Sectish TC, Barger LK, et at. Rates of medication errors among depressed and burnt out residents: prospective cohort study. *BMJ*. 2008;336(7642):488-491.

[147] Murthy VH. Confronting health worker burnout and well-being. *N Engl J Med.* 2022;387(7):577-579.

[148] World Health Organization. Burn-out an "occupational phenomenon": international classification of diseases. May 28, 2019. https://www.who.int/news/item/28-05-2019-burn-out-an-occupational-phenomenon-international-classification-of-diseases. Accessed April 25, 2025.

[149] Hart AM, Crowley C, Janis JE, et al. Survey based assessment of burnout rates among US plastic surgery residents. *Ann Plast Surg*. 2020;85(3):215-220.

[150] McHill AW, Czeisler CA, Shea SA. Resident physician extended work hours and burnout. *Sleep*. 2018;41(8):zsy112.

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[152] Chow OS, Sudarshan M, Maxfield MW, et al. National survey of burnout and distress among cardiothoracic surgery trainees. *Ann Thorac Surg.* 2021;111(6):2066-2071.

[153] Sen S, Kranzler HR, Krystal JH, et al. A prospective cohort study investigating factors associated with depression during medical internship. *Arch Gen Psychiatry.* 2010;67(6):557-565.

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[156] Desai SV, Asch DA, Bellini LM, et al. Education outcomes in a duty-hour flexibility trial in internal medicine. *N Engl J Med.* 2018;378(16):1494-1508.

[157] Rodrigues H, Cobucci R, Oliveira A, et al. Burnout syndrome among medical residents: A systematic review and meta-analysis. *PloS One*. 2018 ;13(11):e0206840.

of depression and 75% met the criteria for burnout.[158] In this study, almost all resident physicians who met the criteria for depression also met the criteria for burnout. Similarly, a survey study published in 2013 found that 22% of 1,508 resident physicians in anesthesiology programs were depressed and 41% were at a high risk of burnout.[159] In this study only 17% of respondents were both depressed and had a high risk of burnout. Likewise, in a survey of 108 resident physicians in cardiothoracic surgery programs, published in 2021, more than 40% of those who responded screened positively for depression and more than half met the criteria for burnout.[160] In a survey of plastic-surgery resident physicians, published in 2020, about two-thirds of the 113 resident physicians who responded met at least one definition of burnout.[161]

In addition to the high levels of burnout and depression across different residency programs, evidence shows that resident physicians have higher rates of mental health conditions after they start their residencies than before they start their training. For instance, a prospective longitudinal cohort study across 13 hospitals in the United States published in 2010, which included 740 interns from pediatric, obstetrics/gynecology, internal medicine, general surgery, and psychiatry residency programs showed that significantly more interns met the criteria for depression during their residency than before their internship.[162] The interns in the study also had higher depressive-symptom scores after residency started than before. Similarly, a 2022 study on new-onset depression, which included 2,793 surgical interns found that 32% of interns who had not previously screened positive for depression developed new-onset depression during their training.[163]

Burnout and depression have repeatedly been linked to extended work hours and sleep deprivation.[164] A prospective study of the employees in an IT company published in 2012 identified less than six hours of sleep as a main risk factor for burnout.[165] Similarly, research among resident physicians indicates that the risk of burnout and depression is higher with

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[159] de Oliveira GS Jr, Chang R, Fitzgerald PC, et al. The prevalence of burnout and depression and their association with adherence to safety and practice standards: A survey of United States anesthesiology trainees. *Anesth Analg.* 2013;117(1):182-193.
[160] Chow OS, Sudarshan M, Maxfield MW, et al. National survey of burnout and distress among cardiothoracic surgery trainees. *Ann Thorac Surg.* 2021;111(6):2066-2071.
[161] Hart AM, Crowley C, Janis JE, Losken A. Survey based assessment of burnout rates among US plastic surgery residents. *Ann Plast Surg.* 2020;85(3):215-220.
[162] Sen S, Kranzler HR, Krystal JH, et al. A prospective cohort study investigating factors associated with depression during medical internship. *Arch Gen Psychiatry*. 2010;67(6):557-565.
[163] Hughes TM, Waljee JF, Fang Y, et al. New-onset depression among surgical interns. *JAMA Surg*. 2022;157(6):543-545.
[164] Martini S, Arfken CL, Balon R. Comparison of burnout among medical residents before and after the implementation of work hours limits. *Acad Psychiatry*. 2006;30(4):352-355.
[165] Söderström M, Jeding K, Ekstedt M, et al. Insufficient sleep predicts clinical burnout. *J Occup Health Psychol*. 2012;17(2):175-183.

insufficient time to sleep and long work hours, including night shifts.[166,167,168] A cohort study that analyzed data from repeating cohorts starting in 2009 through 2020 found that when interns worked more than 90 hours a week they had an almost threefold increased risk of developing depressive symptoms as compared with interns who were working 40-45 hours a week.[169]

Evidence also shows that burnout and other mental health concerns can leave resident physicians feeling exhausted and detached from their work or personal relationships.[170,171] Mental health conditions can lead to impaired cognitive function and decrease resident physicians' effectiveness. Impaired function at work has important implications for patient safety. The prospective cohort study published in 2010, discussed above, found that depressed resident physicians were at a significantly higher risk of reporting medical errors compared with resident physicians who did not have depressive symptoms.[172] Similarly, the previously discussed 2008 prospective cohort study found that resident physicians who met the criteria for depression made 6.2 times as many medication errors per month than those not meeting the criteria.[173] The rate of medical errors, however, was similar between resident physicians meeting the criteria for burnout and those not meeting the criteria. Because burnout has also been linked to emotional fatigue and cynicism among resident physicians, it can contribute to decreased professionalism.[174]

[166] de Oliveira GS Jr, Chang R, Fitzgerald PC, et al. The prevalence of burnout and depression and their association with adherence to safety and practice standards: A survey of United States anesthesiology trainees. *Anesth Analg.* 2013;117(1):182-193.

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[169] Fang Y, Lodi S, Hughes TM, et al. Work hours and depression in US first-year physicians. *N Engl J Med.* 2022;387(16):1522-1524.

[170] Rodrigues H, Cobucci R, Oliveira A, et al. Burnout syndrome among medical residents: A systematic review and meta-analysis. PloS one. 2018 ;13(11):e0206840.

[171] Chow OS, Sudarshan M, Maxfield MW, et al. National survey of burnout and distress among cardiothoracic surgery trainees. *Ann Thorac Surg*. 2021;111(6):2066-2071.

[172] Sen S, Kranzler HR, Krystal JH, et al. A prospective cohort study investigating factors associated with depression during medical internship. *Arch Gen Psychiatry*. 2010;67(6):557-565.

[173] Fahrenkopf AM, Sectish TC, Barger LK, et at. Rates of medication errors among depressed and burnt out residents: prospective cohort study. *BMJ*. 2008;336(7642):488-491.

[174] World Health Organization. Burn-out an "occupational phenomenon": international classification of diseases. May 28, 2019. https://www.who.int/news/item/28-05-2019-burn-out-an-occupational-phenomenon-international-classification-of-diseases. Accessed April 25, 2025.

Part 3: Arguments for Reducing Work Hours, Evidence of Harm to Patients

The detrimental effects of long work hours and extended shifts on patient safety are well documented.[175,176] Sleep deprivation associated with long work hours has been linked to decreased cognitive and clinical performance, trouble with concentration, and reduced motor skills.[177,178,179] Sleep-deprived resident physicians also report becoming inefficient, falling asleep at inappropriate times on the job, and "cutting corners."[180] For these reasons, they are also more likely to report making serious medical errors, have attentional failures, and have higher complication rates than resident physicians with adequate rest. Sleep-deprived resident physicians tend to be more irritable, less composed, and more likely to report conflicts with colleagues.[181,182] Sleep-deprived resident physicians may have reduced empathy for patients and less patience and attention with patients and their families. As previously discussed, fatigued resident physicians often cannot objectively rate their own sleepiness and feel that they can function well despite being sleep deprived.[183] Decades of research supports the beneficial effects of reduced work hours on patient safety.[184,185] In contrast, data suggesting that reduced work hours have no effect or negative effects on patient safety are quite limited.[186,187]

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[175] British Medical Association. Fatigue and sleep deprivation – the impact of different working patterns on doctors. January 2018. https://www.bma.org.uk/media/g1yjtczp/bma-fatigue-sleep-deprivation-briefing-september-2024.pdf. Accessed April 25, 2025.

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[181] Mansukhani MP, Kolla BP, Surani S, et al. Sleep deprivation in resident physicians, work hour limitations, and related outcomes: a systematic review of the literature. *Postgrad Med.* 2012;124(4):241-249.

[182] Trockel MT, Menon NK, Rowe SG, et al. Assessment of physician sleep and wellness, burnout, and clinically significant medical errors. *JAMA Netw Open*. 2020;3(12):e2028111.

[183] Arnedt JT, Owens J, Crouch M, et al. Neurobehavioral performance of residents after heavy night call vs after alcohol ingestion. *JAMA*. 2005;294(9):1025-1033.

[184] Levine AC, Adusumilli J, Landrigan CP. Effects of reducing or eliminating resident work shifts over 16 hours: A systematic review. *Sleep*. 2010;33(8):1043-1053.

[185] Cappuccio FP, Bakewell A, Taggart FM, et al. Implementing a 48 h EWTD-compliant rota for junior doctors in the UK does not compromise patients' safety: assessor-blind pilot comparison. *QJM*. 2009;102(4):271-282.

[186] Bilimoria KY, Chung JW, Hedges LV, et al. National cluster-randomized trial of duty-hour flexibility in surgical training. *N Engl J Med*. 2016;374(8):713-727.

[187] Silber JH, Bellini LM, Shea JA, et al. Patient safety outcomes under flexible and standard resident duty-hour rules. *N Engl J Med.* 2019;380(10):905-914.

3.1. Negative effects of long work hours on patient safety outcomes

In 2004 a national survey about self-reported sleep hours among more than 3,600 interns and second-year resident physicians across several specialties found that resident physicians who had slept five or fewer hours per night were 1.7 times more likely to report making a significant medical error than resident physicians who slept more than five hours per night.[188] More recent data confirm these findings. A multicenter clinical trial published in 2021 compared 294 resident physicians in pediatric intensive care rotations who worked either shifts with extended work hours of 24 hours or more every third or fourth shift, or shifts that were limited to 16 consecutive hours.[189] The trial found that resident physicians working the extended-shift rotations were sleepier, had slower reaction times, were less alert, and had significantly more attentional failures that were associated with serious medical errors.

The negative effects of long work hours are also evident when data for first-year resident physicians and resident physicians in their second or later year are analyzed separately. A prospective randomized trial published in 2004 found that interns in intensive care units who worked extended shifts of 24 hours or more and were on call every third night made 5.6 times as many serious diagnostic errors than when they were working according to an intervention schedule of 63 work hours per week and no extended shifts.[190] Similarly, another intervention study, also published in 2004**,** compared 20 intensive care interns on different rotations.[191] When the interns were in a rotation in which they worked an average of 84.9 hours per week including extended shifts, they had more than double the rate of attentional failures during nighttime shifts and 1.5 times the rate of attentional failures during daytime shifts than they did if they were in a rotation where they worked less than 80 hours a week and shifts of no more than 16 hours.

For more experienced resident physicians (who were at least in their second year of their residency program)**,** a nationwide, prospective cohort study showed that patient and resident physician safety were put at risk when resident physicians worked more than 48 hours a week or worked extended-duration shifts.[192] This study, published in 2023, was based on monthly web-based reports of over 4,800 resident physicians from different specialties in the United States. The researchers found that resident physicians who worked more than 80 hours per week had almost four times higher odds of reporting a medical error than when they worked fewer hours. Moreover, the risk of self-reported medical errors increased significantly after 48 hours of work in a week and doubled when resident physicians worked between 60 and 70 hours a week. When

[188] Baldwin DC Jr, Daugherty SR. Sleep deprivation and fatigue in residency training: results of a national survey of first- and second-year residents. *Sleep.* 2004;27(2):217-223.

[189] Rahman SA, Sullivan JP, Barger LK, et al. Extended work shifts and neurobehavioral performance in resident-physicians. *Pediatrics*. 2021;147(3):e2020009936.

[190] Landrigan CP, Rothschild JM, Cronin JW, et al. Effect of reducing interns' work hours on serious medical errors in intensive care units. *N Engl J Med.* 2004;351(18):1838-1848.

[191] Lockley SW, Cronin JW, Evans EE, et al. Effect of reducing interns' weekly work hours on sleep and attentional failures. *N Engl J Med.* 2004;351(18):1829-1837.

[192] Barger LK, Weaver MD, Sullivan JP, et al. Impact of work schedules of senior resident physicians on patient and resident physician safety: nationwide, prospective cohort study. *BMJ Med.* 2023;2(1):e000320.

resident physicians worked one or more extended-duration shifts a month, despite averaging no more than 80 work hours per week, the risk of medical errors also increased.

3.2. The effects of work-hour regulations on patient safety

Substantial evidence suggests that reducing work hours is beneficial for patient outcomes. For example, a systematic review of the effects of the 2003 work-hour regulations, which was funded by the ACGME, found that these work-hour regulations were associated with significant improvements in patient mortality (including inpatient, 30-day, and overall mortality) and resident well-being.[193]

A 2023 systematic review of 68 studies comparing mortality outcomes before and after ACGME work-hour regulations found that the reduction of work hours overall had a positive effect on patient safety.[194] Specifically, when the researchers compared patient outcomes before and after the 2003 ACGME work-hour policy (which first regulated work hours for all resident physicians), they found that the policy change was associated with a "highly significant" reduction in patient mortality of 11%. Moreover, only one of the 33 studies included in this analysis found that the implementation of the 2003 work-hour restrictions was associated with worse patient safety.

The effect of the 2011 ACGME regulations discussed in this review was less clear, however. Only two of 15 studies demonstrated reduced patient morbidity after this regulation was implemented, while the other studies found no difference in patient outcomes.[195] Similarly, a 2014 observational study including admissions from almost 2.8 million Medicare patients to over 3,000 short-term, acute-care hospitals found no significant changes in mortality rates or readmissions before or after the 2011 work-hour regulation.[196] The authors of both articles speculated that the 2011 policy change might not have had as significant effects on patient outcomes as the 2003 reform, because the 2011 regulations only limited the lengths of continuous shifts for interns, a change that affected only about a quarter of resident physicians. Moreover, little is known about the extent to which residency programs implemented the 2011 regulations and complied with the work-hour reduction policies.

When researchers analyzed the effect of the 2011 work-hour regulations on interns only, the beneficial effects of the changes were evident. An analysis of several prospective cohort studies, published in 2022, evaluated the effect of ACGME's 2011 work-hour standard on medical errors.[197] The researchers compared pooled reports of medical errors of 14,796 first-year resident physicians in five academic years before the implementation of the 2011 ACGME work-hour

[193] Fletcher KE, Reed DA, Arora VM. Patient safety, resident education and resident well-being following implementation of the 2003 ACGME duty hour rules. *J Gen Intern Med*. 2011;26(8):907-919.
[194] Weaver MD, Sullivan JP, Landrigan CP, et al. Systematic review of the impact of physician work schedules on patient safety with meta-analyses of mortality risk. *Jt Comm J Qual Patient Saf*. 2023;49(11):634-647.
[195] *Ibid.*
[196] Patel MS, Volpp KG, Small DS, et al. Association of the 2011 ACGME resident duty hour reforms with mortality and readmissions among hospitalized Medicare patients. *JAMA.* 2014;312(22):2364-2373.
[197] Weaver MD, Landrigan CP, Sullivan JP, et al. National improvements in resident physician-reported patient safety after limiting first-year resident physicians' extended duration work shifts: a pooled analysis of prospective cohort studies. *BMJ Qual Saf*. 2022;32(2):81-89.

regulations with those reported in the three academic years after the policy change. The study found that when interns worked fewer hours, the risk of at least one significant medical error reported in a month decreased by 32% and the risk of medical errors that led to patient deaths was reduced by 63%. In another study that included 13% of all interns in the United States and that was published in 2020, the same group of researchers found that the 2011 work-hour regulations were associated with a 18% reduction in attentional failures.[198]

Despite the extensive evidence that long work hours and extended-duration shifts are detrimental to patient and resident physician safety, other factors during the same timeframe may also have affected safety outcomes. Such factors include changes in medical education, practice patterns, and technologies.[199] However, studies conducted outside of the United States have also found that reduced work hours improved patient safety outcomes. For example, a study published in 2009 found that in the United Kingdom, resident physicians who were working 48 hours per week (in accordance with the European Working Time Directive that limits workweeks to 48 hours for all employees, including resident physicians) made 32.7% fewer medical errors than resident physicians who were working 56 hours per week.[200]

3.3. The FIRST and iCOMPARE trials

The findings of the FIRST and iCOMPARE trials[201,202] led the ACGME to reverse the cap on extended shifts of more than 16 hours for first-year resident physicians. Both trials compared resident physicians enrolled in "standard" residency programs that adhered to the 2011 ACGME work-hour policies with those enrolled in residency programs that followed a "flexible policy." The flexible policy allowed program directors to disregard maximum shift lengths and time off between work shifts as long as the work hours adhered to the ACGME 80-hours-per-week, frequency of on-call duty, and days-off requirements. Before and during the trials, Public Citizen and the American Medical Student Association repeatedly urged ACGME and the Office for

[198] Weaver MD, Landrigan CP, Sullivan JP, et al. The association between resident physician work-hour regulations and physician safety and health. *Am J Med.* 2020;133(7):e343-e354.
[199] Hwang J, Kelz R. Impact of medical education on patient safety: finding the signal through the noise. *BMJ Qual Saf*. 2023;32(2):61-64.
[200] Cappuccio FP, Bakewell A, Taggart FM, et al. Implementing a 48 h EWTD-compliant rota for junior doctors in the UK does not compromise patients' safety: assessor-blind pilot comparison. *QJM*. 2009;102(4):271-282.
[201] Bilimoria KY, Chung JW, Hedges LV, et al. National cluster-randomized trial of duty-hour flexibility in surgical training. *N Engl J Med.* 2016;374(8):713-727.
[202] Silber JH, Bellini LM, Shea JA, et al. Patient safety outcomes under flexible and standard resident duty-hour rules. *N Engl J Med.* 2019;380(10):905-914.

Human Research Protections to suspend the iCOMPARE trial and investigate ethical concerns about both the iCOMPARE and FIRST trials.[203,204,205,206]

Both trials allowed first-year resident physicians to work shifts of 28 consecutive hours or more — nearly twice the maximum number of hours permitted by the ACGME at that time for interns. Resident physicians could not avoid participating in either trial except by leaving their residency programs entirely.[207] Moreover, no informed consent was obtained from "participating" interns (in fact, the FIRST trial investigators claimed that the trial did not involve human subject research).[208] The ACGME extended work-hour waivers and contributed funding for these trials.

Patients seeking care in hospitals with participating residency programs were not informed either about the ongoing trials or that they were being treated by interns who were required to work extended shifts that were not in accordance with the ACGME regulations at the time. In 2011, ACGME's reasoning for limiting shifts to 16 hours was, in part, that "PGY-1 residents make more errors when working longer consecutive hours."[209] Yet the trials were designed to test whether patients treated by resident physicians working longer hours were more likely to die than those cared for by interns working according to the 2011 ACGME work-hour limits. Importantly, the trials did not have a protocol to monitor or mitigate resident physician or patient safety concerns in real time.

The FIRST trial

The FIRST trial, conducted in the academic year 2014-2015, was a national cluster-randomized trial among 117 surgery residency programs to assess several patient safety outcomes, including 30-day rate of postoperative death or serious complications, as well as resident physicians' satisfaction and perception regarding the quality of their education, patient care, and resident physician well-being.[210]

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[203] Public Citizen. Letter to the ACGME regarding Public Citizen's report, bipartisan consensus: the public wants well-rested medical residents to help ensure safe patient care. September 13, 2016. https://www.citizen.org/article/letter-to-the-acgme-regarding-public-citizens-report-bipartisan-consensus-the-public-wants-well-rested-medical-residents-to-help-ensure-safe-patient-care/. Accessed April 25, 2025.

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[205] Public Citizen. Effort to weaken rules on resident physician work hours threatens safety of residents and their patients. March 15, 2016. https://www.citizen.org/news/effort-to-weaken-rules-on-resident-physician-work-hours-threatens-safety-of-residents-and-their-patients/. Accessed April 25, 2025.

[206] Public Citizen. Unethical trials force hundreds of resident doctors nationwide to work dangerously long shifts, placing them and their patients at risk of serious harm**.** November 19, 2015. https://www.citizen.org/news/unethical-trials-force-hundreds-of-resident-doctors-nationwide-to-work-dangerously-long-shifts-placing-them-and-their-patients-at-risk-of-serious-harm/. Accessed April 25, 2025.

[207] Public Citizen. The Unethical iCOMPARE and FIRST trials. May 2016. https://www.citizen.org/wp-content/uploads/publiccitizenfactsheet-icomparefirst.pdf. Accessed April 25, 2025.

[208] *Ibid.*

[209] Accreditation Council for Graduate Medical Education. The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development. 2011. https://www.acgme.org/globalassets/pdfs/jgme-monograph1.pdf. Accessed April 25, 2025.

[210] Bilimoria KY, Chung JW, Hedges LV, et al. National cluster-randomized trial of duty-hour flexibility in surgical training. *N Engl J Med.* 2016;374(8):713-727.

The study's main finding was that there were no significant differences in patient outcomes between patients who were treated by interns working standard hours and those working flexible hours. For example, the rate of death or serious complications in the flexible programs (9.1%) was non-inferior to (not worse than) that in the standard residency programs (9.0%). Although resident physicians assigned to the flexible groups were significantly less likely to leave work during an operation or "hand off" to another resident physician during active patient issues, effects on the outcomes for patients were non-inferior to those in standard programs.

Resident physicians in programs assigned to standard work hours were similarly dissatisfied with the quality of their education (10.7%) compared with resident physicians in programs assigned to flexible work hours (11.0%). There was also no difference in mean scores on the American Board of Surgery In-Training Examination or in the pass rates of the Qualifying Examination or Certifying Examination between the two groups.[211]

Importantly, resident physicians working longer, flexible hours were less satisfied with the effect their work hours had on their well-being.[212] For example, compared with those assigned to standard work hours, those who worked flexible hours were almost four times as likely to report that their work hours had a negative impact on their ability to spend time with family and friends and their ability to rest. They were also almost three times as likely to report negative health effects.[213]

The iCOMPARE trial

The iCOMPARE trial was a randomized trial conducted in 63 internal medicine residency programs during the 2015-2016 academic year.[214] The trial evaluated whether safety outcomes for patients cared for by resident physicians in programs with flexible work hours were non-inferior to those who received care from resident physicians in programs following the 2011 ACGME work-hour standard. The trial also assessed the effect of work hours on sleep outcomes (including alertness, sleep duration, and morning sleepiness)[215] and educational experiences.[216]

For 30-day mortality, the outcomes for patients cared for by resident physicians in programs with longer work hours were non-inferior to the outcomes for patients cared for by resident physicians

[211] Blay E Jr, Hewitt BD, Chung JW, et al. Association between flexible duty hour policies and general surgery resident examination performance: A flexibility in duty hour requirements for surgical trainees (FIRST) trial analysis. *J Am Coll Surg.* 2017;224(2):137-142.
[212] Dahlke AR, Quinn CM, Chung JW, et al. Surgical residents' work hours and well-being in year 2 of the FIRST trial. *N Engl J Med.* 2017;377(2):192-194.
[213] Bilimoria KY, Chung JW, Hedges LV, et al. National cluster-randomized trial of duty-hour flexibility in surgical training. *N Engl J Med*. 2016;374(8):713-727.
[214] Silber JH, Bellini LM, Shea JA, et al. Patient safety outcomes under flexible and standard resident duty-hour rules. *N Engl J Med*. 2019;380(10):905-914.
[215] Basner M, Asch DA, Shea JA, et al. Sleep and alertness in a duty-hour flexibility trial in internal medicine. *N Engl J Med.* 2019;380(10):915-923.
[216] Desai SV, Asch DA, Bellini LM, et al. Education outcomes in a duty-hour flexibility trial in internal medicine. *N Engl J Med*. 2018;378(16):1494-1508.

in programs following the 2011 ACGME work-hour standard.[217] Although the overall sleep duration (per 24 hours) as well as sleepiness among first-year resident physicians working flexible hours were non-inferior to those of resident physicians in the programs following the ACGME work-hour standard, interns in the flexible programs with longer work hours were sleeping less on average, especially during extended overnight shifts.[218] The study also found that interns in the flexible work-hour programs compensated for the loss of sleep during their longer shifts by changing their sleep patterns, for example by sleeping longer on their days off. There were also no significant differences between the groups in terms of how much time interns spent on direct patient care or on education.[219] Although program directors were more satisfied with the flexible work-hour programs, interns in these programs reported less satisfaction with their educational opportunities than those in the programs following the ACGME work-hour standard.

Limitations of the FIRST and iCOMPARE trials

In addition to the ethical concerns discussed above, the FIRST and iCOMPARE trials appear to have been poorly designed and biased to provide evidence that the ACGME's 2011 shift limit of 16 hours for interns was not needed to protect resident physicians and patients.[220] For example, although resident physicians may work beyond the work-hour standard or underreport work hours (which is a concern for all studies trying to assess the effects of work-hour limitations),[221] in the FIRST and iCOMPARE trials flexible work hours were not clearly defined.[222,223,224] Program directors could assign longer shifts but were not required to. As a result, there were large variations in work hours across residency programs. The differences between the work schedules of the two groups and the actual numbers of hours worked were poorly characterized. Moreover, the FIRST trial only evaluated the effect of work hours on patient safety in surgical interns. In the first year of training, surgical resident physicians typically have a lesser role in surgical procedures than in subsequent years.[225] In the iCOMPARE trial, the chosen non-inferiority margin of one percentage point for inferiority has been criticized as "unreasonable."[226] For example, according to a 2023 systematic review, a difference of one percentage point in 30-

[217] Silber JH, Bellini LM, Shea JA, et al. Patient safety outcomes under flexible and standard resident duty-hour rules. *N Engl J Med*. 2019;380(10):905-914.
[218] Basner M, Asch DA, Shea JA, et al. Sleep and alertness in a duty-hour flexibility trial in internal medicine. *N Engl J Med.* 2019;380(10):915-923.
[219] Desai SV, Asch DA, Bellini LM, et al. Education outcomes in a duty-hour flexibility trial in internal medicine. *N Engl J Med*. 2018;378(16):1494-1508.
[220] Public Citizen. Effort to weaken rules on resident physician work hours threatens safety of residents and their patients. March 15, 2016. https://www.citizen.org/news/effort-to-weaken-rules-on-resident-physician-work-hours-threatens-safety-of-residents-and-their-patients/. Accessed April 25, 2025.
[221] Bennett CL, Finch A, Vuong K, et al. Surgical resident duty hours. *N Engl J Med.* 2016;374(24):2399-2401.
[222] McMahon GT. Managing the most precious resource in medicine. *N Engl J Med.* 2018;378(16):1552-1554.
[223] Weaver MD, Landrigan CP, Sullivan JP, et al. National improvements in resident physician-reported patient safety after limiting first-year resident physicians' extended duration work shifts: a pooled analysis of prospective cohort studies. *BMJ Qual Saf*. 2022;32(2):81-89.
[224] Rosenbaum L, Lamas D. Eyes wide open - Examining the data on duty-hour reform. *N Engl J Med.* 2019;380(10):969-970.
[225] Landrigan CP, Rahman SA, Sullivan JP, et al. Effect on patient safety of a resident physician schedule without 24-hour shifts. *N Engl J Med.* 2020;382(26):2514-2523.
[226] Landrigan CP, Czeisler CA. Patient safety under flexible and standard duty-hour rules. *N Engl J Med*. 2019;380(24):2379-2380.

day mortality used in this trial would translate into an increase of mortality due to medical errors of more than 30%, corresponding to at least 39,000 additional deaths.[227,228]

Part 4: Evaluation of Existing Work-Hour Regulations

As discussed above, extensive research indicates that sleep deprivation and fatigue associated with long work hours and extended shifts have a detrimental effect on the health and safety of both resident physicians and patients. At the same time, reducing work hours and especially limiting extended work shifts to no more than 16 hours have been shown to improve resident physician wellness and to decrease their risk of motor vehicle crashes, percutaneous injuries, obstetric complications, and worsening of mental health. As discussed, reduced work hours and limits on extended work shifts also have overall positive effects on patient safety outcomes.

4.1. Effects and limitations of work-hour regulations in the United States

When the ACGME established its 2011 work-hour standards, the council's task force argued that the 2003 reforms had failed to increase the amount of sleep resident physicians got and failed to decrease fatigue.[229] Moreover, as there is also evidence that limiting work hours and shift lengths can increase workload and stress for resident physicians (resident physicians have to complete the same amount of work in less time),[230,231,232] there is concern that reducing work hours might not be the best approach to addressing sleep deprivation with the goal of improving patient outcomes.[233]

A multicenter trial, published in 2020, compared the effects of different work schedules on patient safety.[234] The study found that the same group of pediatric resident physicians in an intensive care unit appeared to make fewer serious errors when they were working longer hours than when they were working shifts of 16 hours or less (79.0 vs. 97.1 serious errors per 1,000

[227] Weaver MD, Sullivan JP, Landrigan CP, et al. Systematic review of the impact of physician work schedules on patient safety with meta-analyses of mortality risk. *Jt Comm J Qual Patient Saf.* 2023;49(11):634-647.
[228] Landrigan CP, Czeisler CA. Patient safety under flexible and standard duty-hour rules. *N Engl J Med*. 2019;380(24):2379-2380.
[229] Nasca TJ, Day SH, Amis ES Jr; ACGME Duty Hour Task Force. The new recommendations on duty hours from the ACGME Task Force. *N Engl J Med*. 2010;363(2):e3.
[230] Rahman SA, Sullivan JP, Barger LK, et al. Extended work shifts and neurobehavioral performance in resident-physicians. *Pediatrics*. 2021;147(3):e2020009936.
[231] Barger LK, Sullivan JP, Blackwell T, et al. Effects on resident work hours, sleep duration, and work experience in a randomized order safety trial evaluating resident-physician schedules (ROSTERS). *Sleep*. 2019;42(8):zsz110.
[232] Hanna J, Gutteridge D, Kudithipudi V. Finding the elusive balance between reducing fatigue and enhancing education: perspectives from American residents. *BMC Med Educ.* 2014;14(Suppl 1):S11.
[233] Bandiera G, Hynes MK, Spadafora SM. Duty hour restrictions: organizational dynamics, systems issues, and the impact on faculty. *BMC Med Educ*. 2014;14(Suppl 1):S5.
[234] Landrigan CP, Rahman SA, Sullivan JP, et al. Effect on patient safety of a resident physician schedule without 24-hour shifts. *N Engl J Med.* 2020;382(26):2514-2523.

patient-days, respectively). However, after the researchers adjusted the number of serious errors by the number of patients a resident physician cared for (8.8 patients when they worked reduced hours and 6.7 patients when they worked extended hours), there was no longer an increase in errors associated with reduced work hours. The authors concluded that finding worse patient outcomes was not related to shorter shifts but instead due to an increase in workload and number of patients cared for. Thus, the implementation of work-hour standards also requires additional regulations regarding workload and staffing.

Numerous studies have demonstrated that the ACGME's limitations of weekly work hours and especially reducing shift lengths to no more than 16 hours help to reduce the hours resident physicians work and to increase the hours they sleep. For example, a 2004 study compared the same 20 interns when they were working in an intensive care rotation with extended work shifts (of 24 hours or more) or in a rotation with shifts of 16 hours or less.[235] The researchers found that 85% of the interns who worked extended shifts had worked more than 80 hours a week, whereas during the limited shift rotation, interns worked on average 19.5 hours less and slept 5.8 hours more per week. During the rotation with shorter shifts, the rate of attentional failures during on-call night shifts was also reduced by more than half.

Similarly, a national prospective cohort study published in 2006 found that after the 2003 ACGME regulations were put in place, work hours among interns decreased from an average of 70.7 hours a week to an average of 66.6 hours, extended work shifts decreased from an average of 32.1 hours to an average of 29.9 hours, and sleep duration increased from an average of 5.9 hours to an average of 6.3 hours per night.[236] However, 29% of interns' workweeks still exceeded 80 hours. Importantly, 12.1% of interns' workweeks exceeded 90 hours and 3.9% exceeded 100 hours.

A cluster-randomized crossover trial (ROSTERS) published in 2019 compared 302 resident physicians taking part in 370 one-month pediatric intensive care unit rotations.[237] The resident physicians worked in rotations with extended-duration shifts of 24 hours or more as well as rotations with work schedules where shifts were limited to a maximum of 16 consecutive hours. When resident physicians worked limited shifts, they were working significantly fewer hours (62 hours) and slept longer (53 hours) than when they worked extended shifts (worked 68 hours a week and only slept 49 hours). Resident physicians in rotations with extended shifts were also significantly more likely to exceed the ACGME's 2017 28-hour work limit in 9% of these shifts, compared with when they were on the restricted schedule (0.1%). The ROSTERS trial also demonstrated that neurobehavioral performance improved in resident physicians on shorter shifts compared to those working extended shifts.

Another prospective study, published in 2020, included 13% of all interns in the United States and compared resident physicians' monthly work hours and several safety outcomes before and

[235] Lockley SW, Cronin JW, Evans EE, et al. Effect of reducing interns' weekly work hours on sleep and attentional failures. *N Engl J Med.* 2004;351(18):1829-1837.

[236] Landrigan CP, Barger LK, Cade BE, et al. Interns' compliance with accreditation council for graduate medical education work-hour limits. *JAMA.* 2006;296(9):1063-1070.

[237] Barger LK, Sullivan JP, Blackwell T, et al. Effects on resident work hours, sleep duration, and work experience in a randomized order safety trial evaluating resident-physician schedules (ROSTERS). *Sleep.* 2019;42(8):zsz110.

after the 2011 ACGME work-hours policy was put in place.[238] The study found that the implementation of the 16-hour shift cap decreased mean work hours from 71 to 62 hours a week and reduced the mean number of shifts that lasted 24 hours or longer from 3.9 times to 0.2 times a month. Importantly, the researchers also found that even one extended work shift a month had a detrimental effect on resident safety (including motor vehicle crashes and percutaneous injuries).

Based on this evidence, limiting work hours through the ACGME work-hour standard, and especially the introduction of a 16-hour cap on shifts, has been successful in increasing sleep time and decreasing shift length and frequency. This evidence underscores the importance of establishing a federal work-hour standard that requires a 16-hour shift cap for all resident physicians.

4.2. Work-hour compliance and violations

The ACGME generally does not specify how resident work hours should be tracked and has not routinely made robust compliance data publicly available.[239,240] However, even when the ACGME makes compliance data public, these data might not accurately reflect the extent of compliance with work-hour regulations, particularly if the information is based on resident self-reports.

Because the ACGME can withdraw the accreditation of residency programs that do not comply with its work-hour regulations, resident physicians have an incentive to underreport violations of their work hours.[241] They may fear punitive actions from their program or the loss of their residency position if their program were to lose its ACGME accreditation. Resident physicians may work more hours than are permitted for various reasons, including because they feel long hours are expected or because they feel pressure to meet patient needs or educational objectives.[242] Studies by researchers who are not affiliated with the ACGME repeatedly found high levels of underreporting and frequent noncompliance with work-hour limits after the 2003, 2011, and 2017 work-hour regulations.

A national prospective cohort study published in 2006 analyzed the compliance of 4,015 interns with work-hour restrictions across specialties.[243] The researchers found that in the year after the implementation of the 2003 ACGME work-hour standard, 83.6% of interns reported that they worked more than the work-hour limits in one or more months. For example, 67.4% reported

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[238] Weaver MD, Landrigan CP, Sullivan JP, et al. The association between resident physician work-hour regulations and physician safety and health. *Am J Med.* 2020;133(7):e343-e354.

[239] Philibert I, Taradejna C. A brief history of duty hours and resident education. In: Philibert I, Amis Jr S, Vasilou E. ACGME task force on quality care and professionalism: The ACGME 2011 duty hour standard. Enhancing Quality of Care, Supervision, and Resident Professional Development. Chicago, IL; 2011: 5-11.

[240] Owei L, Luks VL, Brooks KD, et al. Smart-phone based geofencing: A novel approach to monitoring clinical work hours in surgery residency. *J Surg Educ.* 2021;78(6):e210-e217.

[241] Drolet BC, Schwede M, Bishop KD, et al. Compliance and falsification of duty hours: Reports from residents and program directors. *J Grad Med Educ.* 2013;5(3):368-373.

[242] Bennett CL, Finch A, Vuong K, et al. Surgical resident duty hours. *N Engl J Med.* 2016;374(24):2399-2401.

[243] Landrigan CP, Barger LK, Cade BE, et al. Interns' compliance with accreditation council for graduate medical education work-hour limits. *JAMA.* 2006;296(9):1063-1070.

working shifts of more than 30 consecutive hours, 43.7% reported not having one in seven days off, and 43.0% reported working more than 80 hours a week averaged over four weeks.

Similarly, in a large representative survey of U.S. resident physicians, which included 6,202 resident physicians across multiple specialties published in 2013, only about half of the respondents stated that they were always compliant with the ACGME's 2011 work-hour limits.[244] Also, 42.9% admitted that they falsified their reports at some point, and 18.6% stated that they falsely reported their work hours at least once or twice per month. Program directors who also took part in this survey confirmed that resident physicians were variably compliant with work-hour limits.

A 2017 survey about the 2011 ACGME work-hour standard among 495 resident physicians across 24 specialties found that although most respondents believed that work-hour regulations were reflected in work schedules and enforced in almost all institutions, many resident physicians still violated the work-hour standard.[245] For instance, 11% reported working more than 80 hours per week and 8% worked shifts of more than 28 hours. Of the respondents, 80% felt that in some situations working more than the permitted number of hours was justified.

A national survey of motor vehicle crashes among surgery resident physicians, published in 2021, found frequent violations of ACGME work-hour limits.[246] For instance, 86.2% of resident physicians had worked up to two shifts of more than 28 continuous hours in the prior month, and 13.8% worked three or more such shifts in the most recent month. Of the respondents, 25% stated that they had exceeded the 80-hour-per-week limit in one or two of the previous six months, 8.4% exceeded the limit in three or four months, and 4.8% had exceeded it almost every month.

The 2013 survey discussed above also found that resident physicians with a negative opinion of work-hour limitations were more likely to be noncompliant with the regulations.[247] For example, resident physicians who felt that the 2011 work-hour limitations negatively affected patient safety were 1.5 times more likely to report noncompliance than those who felt the regulations had no or a positive effect on patient safety. The authors concluded that a zero-tolerance policy about falsifying work-hour records is necessary. In sum, the inadequate implementation and enforcement of work-hour limitations may have substantially limited their effectiveness.[248]

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[244] Drolet BC, Schwede M, Bishop KD, et al. Compliance and falsification of duty hours: reports from residents and program directors. *J Grad Med Educ.* 2013;5(3):368-373.

[245] Sandefur BJ, Shewmaker DM, Lohse CM, et al. Perceptions of the 2011 ACGME duty hour requirements among residents in all core programs at a large academic medical center. *BMC Med Educ*. 2017;17(1):199.

[246] Schlick CJ, Hewitt DB, Quinn CM, et al. A national survey of motor vehicle crashes among general surgery residents. *Ann Surg*. 2021;274(6):1001-1008.

[247] Drolet BC, Schwede M, Bishop KD, et al. Compliance and falsification of duty hours: reports from residents and program directors. *J Grad Med Educ.* 2013;5(3):368-373.

[248] Weaver MD, Sullivan JP, Landrigan CP, et al. Systematic review of the impact of physician work schedules on patient safety with meta-analyses of mortality risk. *Jt Comm J Qual Patient Saf.* 2023;49(11):634-647.

4.3. Other countries' responses to resident physician work hours

Resident physicians in the United States typically work much longer hours than resident physicians in many other countries. A qualitative, comparative analysis published in 2023 compared the work hours of resident physicians in 14 high-income countries.[249] The analysis found that although all countries included in the analysis limited the maximum number of weekly work hours, there were different regulations in place, including limiting duration of consecutive work hours and number and duration of extended or overnight shifts. Overall, with the current weekly work-hour limit of 80 to 88 hours, resident physicians in the United States not only had amongst the highest number of weekly work hours, but they also were permitted to work more night shifts per month than resident physicians in other countries.

In contrast to the United States, the European Commission stated in a European Working Time Directive (EWTD) that became effective in 2004 that "[e]very worker has the right to working conditions which respect his or her health, safety and dignity."[250] The EWTD's limits were implemented gradually in different ways (such as maximum hours per shift or number of night shifts per month) across different countries.[251] Since 2009 the weekly working hours for all employees in the European Union, including resident physicians, have been limited to 48 hours a week.

Outside the European Union, resident physicians in many other high-income regions also work fewer hours per shift and fewer hours per week than resident physicians in the United States. For example, in 1990, Quebec (a province in Canada) lowered the limit on consecutive work hours from 36 hours to 24 (in response to Libby Zion's death in the United States, discussed above).[252] In 2011, Quebec further reduced consecutive work hours to an in-house 16-hour call limit, a first in North America. This decision was strongly supported by public opinion.

Moreover, in New Zealand a shift limit of 16 hours has been in place since 1985[253] and in England shifts for resident physicians are limited to 13 hours.[254] Although Australia does not have formal work-hour limitations, resident physicians are cautioned that working for longer than 50 hours a week puts them at higher risks associated with extended work hours as discussed above, such as worse mental health, increased involvement in motor vehicle crashes, disruptions

[249] Maoz Breuer R, Waitzberg R, Breuer A, et al. Work like a doc: a comparison of regulations on residents' working hours in 14 high-income countries. *Health Policy.* 2023;130(April):104753.
[250] European Commission. Working conditions - working time directive. https://ec.europa.eu/social/main.jsp?catId=706&langId=en&intPageId=205. Accessed April 25, 2025.
[251] Maoz Breuer R, Waitzberg R, Breuer A, et al. Work like a doc: a comparison of regulations on residents' working hours in 14 high-income countries. *Health Policy.* 2023;130(April):104753.
[252] Dussault C, Saad N, Carrier J. 16-hour call duty schedules: the Quebec experience. *BMC Med Educ*. 2014;14 (Suppl 1):S10.
[253] Mann S. The evolution of restricted hours of duty for resident medical officers in New Zealand: a personal view. *Clin Med (Lond).* 2005;5(6):650-652.
[254] Maoz Breuer R, Waitzberg R, Breuer A, et al. Work like a doc: a comparison of regulations on residents' working hours in 14 high-income countries. *Health Policy.* 2023;130(April):104753.

of one's social life, and compromised ability to learn, as well as higher risks of cognitive and physical impairment, cardiovascular disease, and negative obstetric outcomes.[255]

Importantly, as will be discussed in more detail below, these more restrictive work-hour limits outside the United States have not negatively affected patient outcomes or educational opportunities for resident physicians.[256,257]

4.4. U.S. work-hour regulations in other industries

The 2017 ACGME work-hour standard requires work hours for resident physicians that are much longer than for employees in most other industries in the United States. In fact, in many other industries' work hours have long been restricted because of safety concerns for employees and the public.

In transportation industries (such as highway, marine, railway, or aviation), fatigue has long been recognized as a key contributing factor for crashes.[258] Moreover, a 2000 consensus statement of an international group of sleep researchers identified long work hours and inadequate sleep as major contributors to fatigue in transport operations and thus the "largest identifiable and preventable cause of accidents in transport operations."[259] An analysis of investigations by the National Transportation Safety Board (NTSB) from 2001 to 2012 found that in about 20% of cases, fatigue was a contibuting factor, probable cause, or a finding of a crash.[260] The analysis also suggests that fatigue-related crashes in transportation industries can be addressed through interventions such as improved work-hour schedules.

The federal government has long recognized the importance of regulating work hours in transportation and other industries. In 1907 in the Hours of Service Act, the United States limited the work hours of railway engineers because of safety concerns.[261] In 1935 the Motor Carrier Act first limited work hours for certrain commercial drivers.[262] Since 1972 the NTSB has issued over

[255] Australian Medical Association. National code of practice – hours of work, shiftwork and rostering for hospital doctors. August 2016. https://ama.com.au/sites/default/files/documents/FINAL_NCP_Hours_of_work_2016.pdf. Accessed April 25, 2025.
[256] Cappuccio FP, Bakewell A, Taggart FM, et al. Implementing a 48 h EWTD-compliant rota for junior doctors in the UK does not compromise patients' safety: assessor-blind pilot comparison. *QJM*. 2009;102(4):271-282.
[257] Collum J, Harrop J, Stokes M. Patient safety and quality of care continue to improve in NHS North West following early implementation of the European Working Time Directive. *QJM.* 2010;103(12):929-940.
[258] Jones CB, Dorrian J, Rajaratnam SMW, et al. Working hours regulations and fatigue in transportation: a comparative analysis. *Saf Sci.* 2005;43(4):225-252.
[259] Akerstedt T. Consensus statement: fatigue and accidents in transport operations. *J Sleep Res.* 2000;9(4):395.
[260] Marcus JH, Rosekind MR. Fatigue in transportation: NTSB investigations and safety recommendations. *Inj Prev.* 2017;23(4):232-238.
[261] Jones CB, Dorrian J, Rajaratnam SMW, et al. Working hours regulations and fatigue in transportation: a comparative analysis. *Saf Sci.* 2005;43(4):225-252.
[262] Federal Register. Hours of service of drivers; driver rest and sleep for safe operations. May 2, 2000. https://www.federalregister.gov/documents/2000/05/02/00-10703/hours-of-service-of-drivers-driver-rest-and-sleep-for-safe-operations#h-15. Accessed April 25, 2025.

200 fatigue-related safety recommendations, including work-hour limitations, to federal agencies and transportation operators.[263]

Under the jurisdiction of the Department of Transportation, several work-hour limits and rest-period requirements for the highway, aviation, railroad, and maritime industries have been established. For example, the Federal Motor Carrier Safety Administration limits property-carrying drivers in commercial industries to driving no more than 11 hours after 10 consecutive hours off duty and passenger-carrying drivers to drive no more than 10 hours after eight consecutive hours off duty.[264] Moreover, property- and passenger-carrying drivers may not drive after having been on duty for 60 hours in seven consecutive days (or 70 hours in eight consecutive days, referred to as 60/70-hour limit). Similarly, the Code of Federal Regulations limits the duty period of a flight crew with one pilot to no more than eight hours of flight time per duty with a minimum rest of 10 to 12 hours after duty and a maximum duty period of 14 hours.[265] According to the Federal Railroad Administration, a train employee may generally not work longer than 12 consecutive hours until that employee has had at least 10 consecutive hours off before duty.[266]

Long-standing federal regulations from the Department of Transportation and other agencies are essential in addressing fatigue-related crashes and have been instrumental in maximizing worker and public safety.[267] The rationale for these regulations has many parallels to the arguments for federal regulation of resident physician work hours.[268]

Part 5: Responses to Concerns About Reducing Work Hours

Some argue that long work hours during medical residency are necessary and have been an integral part of medical training for decades.[269,270,271] One argument is that long work hours are necessary for resident physicians to develop their professional identity and sense of

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[263] Marcus JH, Rosekind MR. Fatigue in transportation: NTSB investigations and safety recommendations. *Inj Prev.* 2017;23(4):232-238.

[264] Federal Motor Carrier Safety Administration. Summary of hours of service regulations. March 28, 2022. https://www.fmcsa.dot.gov/regulations/hours-service/summary-hours-service-regulations. Accessed April 25, 2025.

[265] C.F.R. § 91.1059.

[266] U.S.C. 49 USC § 21103.

[267] Marcus JH, Rosekind MR. Fatigue in transportation: NTSB investigations and safety recommendations. *Inj Prev.* 2017;23(4):232-238.

[268] Public Citizen. Petition to reduce medical resident work hours. September 2, 2010. https://www.citizen.org/article/petition-to-reduce-medical-resident-work-hours-2/. Accessed April 25, 2025.

[269] Accreditation Council for Graduate Medical Education. The ACGME 2011 duty hour standards: enhancing quality of care, supervision, and resident professional development. 2011. https://www.acgme.org/globalassets/pdfs/jgme-monograph1.pdf. Accessed April 25, 2025.

[270] Randle RW, Ahle SL, Elfenbein DM, et al. Surgical trainees' sense of responsibility for patient outcomes: a multi-institutional appraisal. *J Surg Res*. 2020;255(November):58-65.

[271] Miulli DE, Valcore JC. Methods and implications of limiting resident duty hours. *J Am Osteopath Assoc*. 2010;110(7):385-395.

responsibility for the many aspects of patient care and to fully participate in educational and clinical opportunities. Another argument is that reducing work hours would lead to disruptions in the continuity of care and an increased frequency of "handoffs" of care between physicians, thereby introducing more opportunities for medical errors.

Often, these concerns are voiced by residency program directors.[272,273,274] Although program directors have a unique point of view, it is also important to note that they, their staff, and faculty members frequently report that their workload increases when resident physician work hours are reduced.[275,276] Because faculty and other medical staff may have to perform work that had previously been performed by resident physicians,[277] this may influence their views.

Another concern about reductions in work hours for resident physicians is the additional expenditures, such as for hospitals and other health care organizations.[278,279,280] This is mainly due to the costs of hiring additional medical personnel, who often are paid more than resident physicians.[281,282]

The concerns about reducing work hours for resident physicians are discussed in more detail in the following sections. The most important response to these arguments, however, is that resident physicians would continue to work long hours once our petition is granted but would be required to have work schedules that are consistent with protecting the health and safety of resident physicians and the patients they care for. Working 80 hours (without averaging) of the 168 hours in a week are long work hours by any standard. Additional costs to hospitals and health care organizations should be seen in the context of needed expenses to restore or maintain the proper work balance for resident physician education, well-being, and patient care.

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[272] Theobald CN, Stover DG, Choma NN, et al. The effect of reducing maximum shift lengths to 16 hours on internal medicine interns' educational opportunities. *Acad Med*. 2013;88(4):512-518.
[273] Mir HR, Cannada LK, Murray JN, et al. Orthopaedic resident and program director opinions of resident duty hours: a national survey. *J Bone Joint Surg Am*. 2011;93(23):e1421-e1429.
[274] Coverdill JE, Alseidi A, Borgstrom DC, et al. Assessing the 16 hour intern shift limit: Results of a multi-center, mixed-methods study of residents and faculty in general surgery. *Am J Surg.* 2018;215(2):326-330.
[275] Drolet BC, Khokhar MT, Fischer SA. The 2011 duty-hour requirements—a survey of residency program directors. *N Engl J Med.* 2013;368(8):694-697.
[276] Bandiera G, Hynes MK, Spadafora SM. Duty hour restrictions: organizational dynamics, systems issues, and the impact on faculty. *BMC Med Educ*. 2014;14(Suppl 1):S5.
[277] Miulli DE, Valcore JC. Methods and implications of limiting resident duty hours. *J Am Osteopath Assoc*. 2010;110(7):385-395.
[278] Blum AB, Raiszadeh F, Shea S, et al. US public opinion regarding proposed limits on resident physician work hours. *BMC Med*. 2010;8(June 1):33.
[279] Mansukhani MP, Kolla BP, Surani S, et al. Sleep deprivation in resident physicians, work hour limitations, and related outcomes: a systematic review of the literature. *Postgrad Med*. 2012;124(4):241-249.
[280] Marcus CL, Loughlin GM. Effect of sleep deprivation on driving safety in housestaff. *Sleep*. 1996;19(10):763-766.
[281] Romano M. Lightening their load. *Mod Healthc.* 2003;33(17):32-35,47.
[282] DeMarco DM, Forster R, Gakis T, et al. Eliminating residents increases the cost of care. *J Grad Med Educ*. 2017;9(4):514- 517.

5.1. Lack of effect of work-hour regulations on medical education

As stated above, one of the arguments against reducing work hours is that resident physicians will have fewer educational opportunities and a decreased quality of training.[283] Although a few studies support this view, there is far more evidence to the contrary. In fact, many studies have demonstrated that improvements in resident physician quality of life and patient safety did not come at the price of significantly reducing educational and clinical experiences.[284]

For example, a systematic review of 72 studies published in 2011 suggested that the reduction of working hours to less than 80 hours per week in the United States did not have a negative effect on training opportunities overall.[285] Similarly, a national survey-based study published in 2014 compared the educational and clinical experiences of 316 pediatric interns during their neonatal rotations who worked shifts of 16 hours or more in 2011 with 509 interns who worked shifts of 16 hours or less in 2012.[286] The researchers found that the 2011 ACGME work-hour regulation did not lead to significantly different experiences. Although interns attended fewer grand rounds, lectures, and mock resuscitations, after the 16-hour cap there was no difference between the cohorts in the proportion of correct responses on a knowledge-based multiple-choice test. Importantly, there was also no difference in the number of patients they saw or how many deliveries and procedures they attended.

The FIRST trial (despite the fact it was poorly designed and raised ethical concerns, as discussed above) also confirmed that resident physicians who worked shorter shifts did not have different mean scores or pass rates in several tests (including the American Board of Surgery In-Training Examination, the Qualifying Examination, and Certifying Examination) than those working flexible, longer shifts.[287] Additionally, a 2015 study conducted in the Netherlands found that even after the implementation of the 48-hour workweek as part of the European Working Time Directive, the number of surgical procedures performed by resident physicians stayed largely the same.[288]

There is additional evidence that work-hour limitations have had either no effect or even a positive effect on medical education. A systematic review published in 2010 found that, overall, reduced work hours did not have a significant effect on medical education outcomes (nine of 14

[283] Bolster L, Rourke L. The effect of restricting residents' duty hours on patient safety, resident well-being, and resident education: An updated systematic review. *J Grad Med Educ*. 2015;7(3):349-363.

[284] Levine AC, Adusumilli J, Landrigan CP. Effects of reducing or eliminating resident work shifts over 16 hours: A systematic review. *Sleep.* 2010;33(8):1043-1053.

[285] Moonesinghe SR, Lowery J, Shahi N, et al. Impact of reduction in working hours for doctors in training on postgraduate medical education and patients' outcomes: systematic review. *BMJ.* 2011;342(March 22):d1580.

[286] DeLaroche A, Riggs T, Maisels MJ. Impact of the new 16-hour duty period on pediatric interns' neonatal education. *Clin Pediatr.* 2014;53(1):51-59.

[287] Blay E Jr, Hewitt BD, Chung JW, et al. Association between flexible duty hour policies and general surgery resident examination performance: A flexibility in duty hour requirements for surgical trainees (FIRST) trial analysis. *J Am Coll Surg.* 2017;224(2):137-142.

[288] Hopmans CJ, den Hoed PT, van der Laan L, et al. Impact of the European Working Time Directive (EWTD) on the operative experience of surgery residents. *Surgery*. 2015;157(4):634-641.

studies).[289] Four studies, however, found significant improvements (such as increased test scores or higher number of operative or surgical cases). Only one study found worse educational outcomes.

A 2013 study compared the educational opportunities of 47 internal medicine interns in one medical center before the ACGME 16-hour shift limitation in 2011 with those of 50 interns after the implementation of this shift limitation.[290] The researchers concluded that because the median number of selected procedures performed remained the same before and after the 2011 policy change, the 16-hour cap did not reduce the clinical experiences of interns. Moreover, interns cared for significantly more patients (on average 140 per intern over 24 weeks) after the implementation than before the work-hour limit (on average 118 patients per intern). After the 16-hour cap was implemented, interns also wrote significantly longer and more detailed notes and were more likely to attend the weekly chief resident conference.

Another study, published in 2015, retrospectively reviewed resident performance on the American Board of Surgery In-Training Examination and their surgical-case volume in one institution over five years of such training.[291] The researchers compared certain outcome measures of surgical training among 169 general surgery resident physicians before the 2011 ACGME work-hour standard (July 2008-June 2011) with those of 115 resident physicians in the years after implementation (July 2011-June 2013). Not only did study examination scores not significantly differ before and after the 2011 policy reform, case volumes also significantly increased after the work-hour limitations. For example, chief resident physicians finished their programs with 1,062 major cases after the work-hour limitations, compared with 945 cases for their counterparts before the work-hour limitations. The positive effect of the work-hour limitation on educational opportunities may have been facilitated by an organizational restructuring of the institute, which included hiring additional staff (such as nurse practitioners and physician assistants who, under the supervision of senior resident physicians, could provide coverage in place of interns during night shifts).

5.2. Lack of effect of work-hour regulations on the continuity of patient care

As stated above, there is a false concern that work-hour regulations may have negative effects on patient care, including the continuity of care. Several studies indicate, however, that limiting work hours for resident physicians did not lead to decreased time spent in direct patient care.[292]

[289] Levine AC, Adusumilli J, Landrigan CP. Effects of reducing or eliminating resident work shifts over 16 hours: A systematic review. *Sleep.* 2010;33(8):1043-1053.

[290] Theobald CN, Stover DG, Choma NN, et al. The effect of reducing maximum shift lengths to 16 hours on internal medicine interns' educational opportunities. *Acad Med.* 2013;88(4):512-518.

[291] Condren AB, Divino CM. Effect of 2011 Accreditation Council for Graduate Medical Education duty-hour regulations on objective measures of surgical training. *J Surg Educ.* 2015;72(5):855-861.

[292] Weaver MD, Landrigan CP, Sullivan JP, et al. National improvements in resident physician-reported patient safety after limiting first-year resident physicians' extended duration work shifts: a pooled analysis of prospective cohort studies. *BMJ Qual Saf*. 2022;32(2):81-89.

For example, as part of the iCOMPARE trial the researchers assumed that flexible, longer work hours would allow interns to spend more time in direct patient care than working according to the 2011 ACGME work-hour standard.[293] The study (despite the serious concerns about its biased study design discussed above) found, however, that internal medicine interns in the standard program spent a comparable amount of time in direct patient care (11.8%) to those in the flexible work-hour model (13.0%). Importantly, interns who worked flexible hours were more likely to be dissatisfied with several aspects of their training, such as the quality of their education, their overall well-being, and the effect the residency schedule had on their personal lives. Notably, unlike interns, the directors of flexible residency programs were more satisfied with the educational opportunities for their resident physicians than directors of standard programs.

Similarly, although surgical resident physicians working standard hours in the FIRST trial were more likely to report leaving during an operation or handing off active patient issues than those who were working flexible hours, the researchers did not demonstrate that this had a significant impact on patient outcomes.[294]

Moreover, a 2010 study conducted in one region in England (NHS North West) that had implemented the 48-hour EWTD work-hour restrictions one year ahead of schedule found that limiting work hours had not negatively affected quality of care and patient safety.[295] When the researchers compared several outcome measures (such as increases in length of hospitalization, rates of readmission, or mortality) in this region with national data for that year, they found no significant differences. In fact, an analysis of the average length of stay found that the region with shorter work hours performed better than the national average, where longer work hours were still standard.

As discussed above, shorter shifts for resident physicians can often lead to an increased number of handoffs of patient care between physicians. Especially if handoffs are poorly executed, the concern is that critical information may not be communicated, contributing to medical errors and patient harm.[296,297] An assumption underlying this concern is that handoffs between physicians are inherently more detrimental to patient safety than resident physician fatigue.[298] Handoffs, however, occur regardless of shift length. In fact, the likelihood of failing to communicate critical information may be higher if resident physicians have worked continuously for 24 hours or more rather than working a 16-hour shift.

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[293] Desai SV, Asch DA, Bellini LM, et al. Education outcomes in a duty-hour flexibility trial in internal medicine. *N Engl J Med*. 2018;378(16):1494-1508.

[294] Bilimoria KY, Chung JW, Hedges LV, et al. National cluster-randomized trial of duty-hour flexibility in surgical training. *N Engl J Med.* 2016;374(8):713-727.

[295] Collum J, Harrop J, Stokes M. Patient safety and quality of care continue to improve in NHS North West following early implementation of the European Working Time Directive. *QJM.* 2010;103(12):929-940.

[296] Choma NN, Vasilevskis EE, Sponsler KC, et al. Effect of the ACGME 16-hour rule on efficiency and quality of care: duty hours 2.0. *JAMA Intern Med.* 2013;173(9):819-821.

[297] Starmer AJ, Spector ND, Srivastava R, et al. Changes in medical errors after implementation of a handoff program. *N Engl J Med.* 2014;371(19):1803-1812.

[298] Sandefur BJ, Shewmaker DM, Lohse CM, et al. Perceptions of the 2011 ACGME duty hour requirements among residents in all core programs at a large academic medical center. *BMC Med Educ.* 2017;17(1):199.

A retrospective analysis published in 2013 found that although the number of handoffs increased after the 2011 ACGME policy change, there was not a significant effect on quality of care or efficiency among medical inpatients not requiring intensive care.[299] A retrospective cohort study published in 2017 compared the types of medical errors that occurred while surgical resident physicians at one institution were working either standard hours or flexible hours.[300] The researchers found that there were no differences in the types of errors between the periods and no differences in mortality or complication rates. Importantly, flexible hours were not associated with fewer errors due to handoffs.

A prospective intervention study published in 2014 found that errors associated with handoffs can be significantly reduced with a program designed to optimize handoffs through improved quality of oral and written communication during handoffs between shifts.[301] Specifically, the researchers compared 5,516 patient admissions before the program with 5,224 patient admissions after the intervention and found that handoff optimization was associated with a decrease of 23% in medical errors and a decrease of 30% in preventable adverse events. Implementation of the program did not affect the workflow, because resident physicians spent a similar percentage of time with patients and their families. Further, the intervention did not change the duration of the handoffs.

5.3. Perspectives of program directors and resident physicians

Residency programs are heterogeneous, varying by size and specialty. A national survey of residency program directors published in 2010 found that most directors approved of some work-hour regulations (such as an 80-hour workweek or one day per week off).[302] However, other regulations, especially the capping of work shifts at 16 hours, were viewed more critically. The survey also found that attitudes towards work hours differed across specialties, with program directors of pediatrics or internal medicine programs viewing limiting work hours more positively than directors of surgery programs.

A survey of 549 pediatrics, internal medicine, or general surgery residency program directors, published in 2013, found that most program directors did not view the 2011 ACGME regulations as changing any of several important aspects of residency programs, such as exam scores and the balance of education and service.[303] Instead, approximately half of the program directors viewed the reductions in works hours as leading to improvements in the quality of life of resident physicians. Surveys of resident physicians have found that most are satisfied with work-hour

[299] Choma NN, Vasilevskis EE, Sponsler KC, et al. Effect of the ACGME 16-hour rule on efficiency and quality of care: duty hours 2.0. *JAMA Intern Med.* 2013;173(9):819-821.
[300] Anderson JE, Goodman LF, Jensen GW, et al. Restrictions on surgical resident shift length does not impact type of medical errors. *J Surg Res*. 2017;212(May 15):8-14.
[301] Starmer AJ, Spector ND, Srivastava R, et al. Changes in medical errors after implementation of a handoff program. *N Engl J Med.* 2014;371(19):1803-1812.
[302] Antiel RM, Thompson SM, Reed DA, et al. ACGME duty-hour recommendations—a national survey of residency program directors. *N Engl J Med.* 2010;363(8):e12.
[303] Drolet BC, Khokhar MT, Fischer SA. The 2011 duty-hour requirements—a survey of residency program directors. *N Engl J Med.* 2013;368(8):694-697.

reductions because they increased their quality of life[304] and had a positive effect on their training.[305]

As discussed above, the views of resident physicians and program directors often differ on key issues, such as satisfaction with flexible (and longer) or standard work hours.[306] One explanation for this mismatch is that some program directors may be unaware of, or insufficiently responsive to, their resident physicians' needs.[307] They may therefore make "well-intentioned but ultimately ill-informed decisions about the design and delivery of the residency programs", especially given the evidence of the positive effects of reduced work hours on the health and safety of resident physicians and their patients.

The opinions of program directors can also affect the views of resident physicians about work-hour regulations. A national survey study, published in 2011, including responses from 1,314 orthopedic resident physicians and 185 residency program directors, found that although 70% of resident physicians and 79% of program directors believed reducing work hours increased the number of handoffs that would be detrimental to patient care, 71% of resident physicians felt that a 80-hour workweek was still appropriate, whereas only 38% of program directors agreed.[308] Moreover, 70% of program directors, but only 24% of resident physicians, thought that the ACGME's 2003 work-hour regulation had not improved patient care. Although 60% of resident physicians reported improvements in their ability to function after the work-hour regulation was implemented, only 17% of the program directors agreed.

A survey, published in 2020, with responses from 123 resident physicians and 136 faculty of general surgery residency programs found a similar mismatch of perceptions.[309] For example, although 92.6% of resident physicians routinely checked on their patients while off duty, faculty thought that only about 36.8% did. Only about a quarter of faculty thought that resident physicians had a similar or higher degree of "patient ownership" as they had themselves.

In aggregate, the available studies indicate that the concerns about work-hour restrictions for resident physicians are not based on facts but on beliefs that extended, less-restricted work hours are required because it has always been this way, and that they are a necessary price that resident physicians need to pay to demonstrate their "professional commitment" to patients and their medical training.[310]

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[304] Miulli DE, Valcore JC. Methods and implications of limiting resident duty hours. *J Am Osteopath Assoc*. 2010;110(7):385-395.

[305] Sandefur BJ, Shewmaker DM, Lohse CM, et al. Perceptions of the 2011 ACGME duty hour requirements among residents in all core programs at a large academic medical center. *BMC Med Educ*. 2017;17(1):199.

[306] Desai SV, Asch DA, Bellini LM, et al. Education outcomes in a duty-hour flexibility trial in internal medicine. *N Engl J Med.* 2018;378(16):1494-1508.

[307] McMahon GT. Managing the most precious resource in medicine. *N Engl J Med.* 2018;378(16):1552-1554.

[308] Mir HR, Cannada LK, Murray JN, et al. Orthopaedic resident and program director opinions of resident duty hours: a national survey. *J Bone Joint Surg Am*. 2011;93(23):e1421-e1429.

[309] Randle RW, Ahle SL, Elfenbein DM, et al. Surgical trainees' sense of responsibility for patient outcomes: a multi-institutional appraisal. *J Surg Res*. 2020;255(November):58-65.

[310] Veazey Brooks J, Bosk CL. Remaking surgical socialization: work hour restrictions, rites of passage, and occupational identity. *Soc Sci Med.* 2012;75(9):1625-1632.

5.4. The perspective of the public

Public-opinion surveys have consistently found that the public does not want to be cared for by resident physicians who have worked extended shifts and are sleep deprived. Moreover, the public does not approve of the long work hours and extended shifts permitted in residency programs.

Over the last decade, public opinion on this issue has changed little. Nationally representative surveys repeatedly find that adults in the United States disapprove of the current work hours of resident physicians.[311,312] The public also believes that further limits on work hours would be an effective way to reduce medical errors and that the hours worked by resident physicians are longer than what most believe to be safe.

This finding is of particular interest because most of the public tends to seriously underestimate the hours resident physicians typically are permitted to work. For instance, a representative survey published in 2010 found that the public estimated that shifts last about 13 hours and that resident physicians worked about 58 hours a week.[313] In fact, in 2010, under the ACGME's 2003 work-hour standard, resident physicians were allowed to work extended shifts of up to 30 hours once or twice a week and a total of up to 88 hours a week, although, as discussed above, many resident physicians violated these standards and frequently worked even longer hours.

Importantly, the public feels that they should be told if their treating resident physician had worked an extended shift without sleep. In fact, most respondents reported that they would not want to be treated by a sleep-deprived resident physician.[314] In 2016 a representative national poll of likely U.S. voters commissioned by Public Citizen found that about 80% of the respondents were in support of lowering shift limits from 28 hours to a maximum of 16 hours for all resident physicians in their second year or above. The same poll also found that 86% of the public opposed the proposal to eliminate the 16-hour cap on shifts for interns (the 16-hour cap that the ACGME rolled back in 2017).

Similarly, a nationally representative poll conducted in 2022 and published in 2024 found that 97% of respondents believed that resident physicians should not work shifts longer than 24 hours and 96% believed that the current resident workweek of 80 hours was too long.[315] Two-thirds of the respondents thought that resident physicians should work no more than 12 consecutive hours per shift and their workweeks should be no more than 59 hours. Across these two polls, less than 6% of the public supported work shifts that are scheduled for 24 hours or longer and 80 or more work hours per week.

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[311] Weaver MD, Barger LK, Sullivan JP, et al. Public opinion of resident physician work hours in 2022. *Sleep Health*. 2024;10(1S):S194-S200.

[312] Public Citizen. Bipartisan consensus: The public wants well-rested medical residents to help ensure safe patient care. September 13, 2016. https://www.citizen.org/wp-content/uploads/hrg2335a.pdf. Accessed April 25, 2025.

[313] Blum AB, Raiszadeh F, Shea S, et al. US public opinion regarding proposed limits on resident physician work hours. *BMC Med.* 2010;8(June 1):33.

[314] *Ibid*.

[315] Weaver MD, Barger LK, Sullivan JP, et al. Public opinion of resident physician work hours in 2022. *Sleep Health*. 2024;10(1S):S194-S200.

Although often ignored, public opinion is a very relevant consideration for resident physician work-hour regulations. The public pays indirectly for medical education through taxes and Medicare premiums that fund residency programs and directly by paying for health care services.[316] At the same time, long work hours for resident physicians can contribute to patient harms, as discussed above.

Part 6: Petitioners' Request

Public Citizen and the American Medical Student Association request that CMS applies the following work-hour regulations to resident physicians in all residency and subspecialty fellowship programs:

(1) A limit of 80 hours of work in each and every workweek, without averaging;
(2) A limit of 16 consecutive hours worked in one shift for *all* resident physicians and subspecialty resident physicians, with no exceptions;
(3) At least one 24-hour period of time off work per week (no averaging) and one 48-hour period of time off work per month, no averaging;
(4) In-hospital on-call frequency no more than once every three nights, no averaging;
(5) A minimum of at least 10 hours off work after a day shift and a minimum of 12 hours off work after a night shift; and
(6) A maximum of four consecutive night shifts with a minimum of 48 hours off after a sequence of three or four night shifts.

Work hours include any time asleep at the work site. Time off work is time away from the hospital or other work site while not on call. As stated by the ACGME, any time resident physicians spend on "at-home call must count toward the 80-hour maximum weekly limit."[317]

Petitioners' requests shall not be construed to require or permit a resident physician to abandon a patient in need of emergency or critical care. In a patient care emergency and when there are no available alternatives, the resident physician's or subspecialty resident physician's work may exceed the maximum 16-consecutive-hour shift or 80-hour-per-week limit for this reason only. Regardless, resident physicians should not be scheduled to be at a worksite more than the 16-hour-per-day or 80-hour-per-week limit.

Petitioners' requests differ from the current ACGME work-hour standards, effective as of 2022, in several ways: First, whereas the most recent ACGME work-standard policy calls for an 80-hour workweek averaged over a four-week period, petitioners' requests are for an 80-hour workweek that is not averaged. Allowing resident physicians to work "beyond their scheduled

[316] Weaver MD, Barger LK, Sullivan JP, et al. Public opinion of resident physician work hours in 2022. *Sleep Health*. 2024;10(1S):S194-S200.

[317] Accreditation Council for Graduate Medical Education. ACGME common program requirements (residency). September 17, 2022. https://www.acgme.org/globalassets/pfassets/programrequirements/cprresidency_2023.pdf. Accessed April 25, 2025.

work periods to care for a patient or participate in an educational activity," as argued by the ACGME, is not consistent with minimizing harm to physicians and patients, and exceptions to an 80-hour week should not be granted to any residency program. At present, the ACGME may grant "rotation-specific exceptions for up to 10 percent or a maximum of 88 clinical and educational work hours to individual programs based on a sound educational rationale."[318] As stated previously, the petitioners request that the same standard apply to all rotations and specialties because exceptions other than for emergency or critical care as discussed above undermine the purpose of the 80-hour workweek limit. Thus, the petitioners request an 80-hour limit of work per week be applied to all residency and subspecialty fellowship programs, with no exceptions, across specialties.

Second, the ACGME rules allow resident physicians to work up to 28 consecutive hours. The petitioners request a maximum continuous shift time of 16 hours (as was implemented by the ACGME between 2011 and 2017 for interns only) for all resident physicians, without exceptions.

Third, the current ACGME work-hour standard provides for a minimum of one day off per week when averaged over four weeks. Petitioners request that resident physicians have at least one day (24-hour period) off work per week without averaging as well as at least one two-day (48-hour) period of time off work per month without averaging.

Fourth, the petitioners request that in-hospital on-call frequency should be no more than every third night without averaging for all resident physicians, not averaged over a four-week period as the ACGME currently permits.

Fifth, as recommended by the IOM,[319] resident physicians should have a minimum of 10 hours off work after a daytime work shift (that is not part of an extended shift) and 12 hours off work after a night shift (that is not part of an extended shift). At present, the ACGME work-hour standard requires only eight hours off between work and education periods,[320] which contributes to inadequate sleep on a regular basis once commuting time and personal responsibilities are accounted for.

Finally, although the ACGME in the past allowed resident physicians to work up to six night shifts in a row,[321] at present the ACGME does not specify a maximum number of consecutive night shifts. ACGME's rules state that the "maximum number of consecutive weeks of night

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[318] *Ibid.*

[319] Institute of Medicine. Committee on Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedule to Improve Patient Safety. Resident Duty Hours: Enhancing Sleep, Supervision, and Safety, National Research Council. Ulmer C, Miller Wolman D, Johns MME, editors. Washington (DC): The National Academies Press; 2009.

[320] Accreditation Council for Graduate Medical Education. ACGME common program requirements (residency). September 17, 2022. https://www.acgme.org/globalassets/pfassets/programrequirements/cprresidency_2023.pdf. Accessed April 25, 2025.

[321] Riebschleger, M, Nasca TJ. New duty hour limits: discussion and justification. https://www.acgme.org/globalassets/pdfs/jgme-11-00-29-37.pdf. Accessed April 25, 2025.

float… may be further specified by the Review Committee."[322] The petitioners maintain that resident physicians should not be permitted to work more than four consecutive night shifts, as the IOM recommended.[323] Moreover, after three to four consecutive nights of work, petitioners request that a 48-hour period without work be required to allow for recovery sleep and prevent the buildup of sleep debt.

Enforcement

Petitioners request that strict enforcement accompany the regulations. Previous efforts to limit resident physician work hours have been undermined by inadequate enforcement. Resident physician work schedules and work hours should be accurately recorded and maintained as records by the residency programs and the hospitals and other health care facilities where resident physicians work. These records should be fully available for inspection by CMS:

(1) CMS should establish an official, confidential, and easy-to-use procedure for reporting work-hour violations for resident physicians and widely publicize this reporting procedure.
(2) CMS should conduct unannounced and frequent inspections of residency programs for compliance with work-hour regulations.
(3) CMS should establish enforcement mechanisms of work-hour regulations, including provisions for fines of sufficient amounts to deter violations; financial penalties to teaching hospitals that do not adequately monitor, enforce, and otherwise comply with the regulations; and public reporting of violations.

Conclusion

As outlined in this petition, as well as Public Citizen's previous petitions in 2001[324] and 2010,[325] there is a substantial body of evidence that convincingly demonstrates that long work hours and extended shifts for resident physicians are associated with sleep deprivation and fatigue. Moreover, these excessive work schedules have been shown to increase numerous risks for resident physicians' lives and health — including an increased risk of being involved in motor vehicle crashes, higher risks of negative mental health outcomes, higher risks of obstetric complications among pregnant resident physicians, and higher risk of percutaneous injuries. Sleep-impaired resident physicians also pose a risk for the patients in their care because sleep

[322] Accreditation Council for Graduate Medical Education. ACGME common program requirements (residency). September 17, 2022. https://www.acgme.org/globalassets/pfassets/programrequirements/cprresidency_2023.pdf. Accessed April 25, 2025.
[323] Institute of Medicine. Committee on Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedule to Improve Patient Safety. Resident Duty Hours: Enhancing Sleep, Supervision, and Safety, National Research Council. Ulmer C, Miller Wolman D, Johns MME, editors. Washington (DC): The National Academies Press; 2009.
[324] Public Citizen. Petition requesting medical residents work hour limits. April 30, 2001. https://www.citizen.org/article/petition-requesting-medical-residents-work-hour-limits/. Accessed April 25, 2025.
[325] Public Citizen. Petition to reduce medical resident work hours. September 2, 2010. https://www.citizen.org/article/petition-to-reduce-medical-resident-work-hours-2/. Accessed April 25, 2025.

deprivation associated with long work hours has been linked to increased medical errors and preventable adverse events, leading to worse patient safety outcomes.

In 2003, 2011, and again in 2017 the ACGME failed to demonstrate that it can establish and enforce work-hour standards that would ensure "safe and healthful working conditions"[326] for resident physicians. Resident physicians have a right to be protected by CMS. As specified in Title 42 of the Code of Federal Regulations, hospitals participating in Medicare must meet certain requirements that may be amended "if they are found necessary in the interest of the health and safety of the individuals who are furnished services in hospitals."[327]

We respectfully request that CMS adopts the evidence-based work-hour standards requested in this petition, which are based on those suggested by the IOM report and represent an expansion of those put forth by the ACGME.

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[326] 29 U.S.C. § 651-78.
[327] 42 C.F.R. § 482.1.