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Billing Code: 4153-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No.: HHS-OCR-2021-0002]

Centers for Medicare & Medicaid Services

42 CFR Parts 482 and 489

Office of the Secretary

45 CFR Part 84

RIN: 0945-AA14

**Special Responsibilities of Medicare Hospitals in Emergency Cases and
Discrimination on the Basis of Disability in Critical Health and Human Service
Programs or Activities**

AGENCY: Centers for Medicare & Medicaid Services (CMS); Office for Civil Rights (OCR), Office of the Secretary, HHS.

ACTION: Proposed rule.

SUMMARY: The Department of Health and Human Services (“the Department” or “HHS”) is committed to protecting the civil rights and equal dignity of persons with disabilities under Section 504 of the Rehabilitation Act of 1973 (“Section 504”) and ensuring proper procedures are followed with respect to infants protected by the Emergency Medical Treatment and Labor Act (EMTALA), and are followed with respect

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to infants and adults under Centers for Medicare & Medicaid Services (CMS) hospital facility regulations (Facility Regulations) including those required by the Social Security Act.

To robustly enforce these provisions, the Department proposes to update and amend these three regulations to clarify that, with respect to infants, protections under Section 504, EMTALA, and the Facility Regulations apply to infants born alive, and that Section 504 precludes the denial of care to newborn infants with disabilities whose parents or guardians consent to treatment. With respect to individuals, including adults and infants, the Department also proposes to clarify that protections under Section 504 apply to the discriminatory withdrawal or withholding of requested life-saving or life-sustaining care of individuals with disabilities; to prohibit, under Section 504 and Facility Regulations, undue influence or steering of individuals toward the withdrawal of life-saving or life-sustaining care, or toward the provision of life-ending services, on the basis of disability; to clarify that provider obligations under the Facility Regulations include informing a patient or patient's legal representative when an unsolicited "Do Not Resuscitate" order has been placed for the patient; and to make other changes consistent with longstanding nondiscrimination requirements with respect to individuals with disabilities.

DATES: Comments on this proposed rule must be received by [INSERT DATE 60

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DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments to this proposed rule, identified by RIN

0945-AA14, by any of the following methods:

- *Federal eRulemaking Portal.* You may submit electronic comments at <http://www.regulations.gov> by searching for the Docket ID number HHS-OCR-2021-0002. Follow the instructions at <http://www.regulations.gov> online for submitting comments at <http://www.regulations.gov>.

- *Regular, Express, or Overnight Mail:* You may mail comments to U.S. Department of Health and Human Services, Office for Civil Rights, Attention: Disability NPRM, RIN 0945-AA14, Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue, S.W., Washington, D.C., 20201.

- *Hand Delivery / Courier:* You may hand deliver comments to the U.S. Department of Health and Human Services, Office for Civil Rights, Attention: Disability NPRM, RIN 0945-AA14, Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue, S.W., Washington, D.C., 20201.

All comments sent by these methods and received or officially postmarked by the due date specified above will be posted without change to <http://www.regulations.gov>, including any personal information provided, and such posting may occur before or after the closing of the comment period.

We will consider all comments received or officially postmarked by the date

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specified above, but, because of the large number of public comments we normally receive on *Federal Register* documents, we are not able to provide individual acknowledgements of receipt.

Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to ask building security for further instructions on leaving their comments at the building. Electronic comments with attachments should be in Microsoft Word or Excel; however, we prefer Microsoft Word.

Please note that comments submitted by fax or email, and those submitted or postmarked after the comment period, will not be accepted.

Docket: For complete access to background documents or posted comments, go to <http://www.regulations.gov> and search for Docket ID number HHS-OCR-2021-0002.

FOR FURTHER INFORMATION CONTACT: Carla Carter at (800) 368-1019 or (800) 537-7697 (TDD).

SUPPLEMENTARY INFORMATION:

I. Summary

A. Purpose

People with disabilities have historically faced discrimination in the health care system, often rooted in the false assertion that life with a disability is not worth living.

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Executive Order 13952, “Protecting Vulnerable Newborn and Infant Children,” affirmed that every infant, “no matter the circumstances of his or her birth, has the same dignity and the same rights as every other individual and is entitled to the same protections under Federal law.”¹ The E.O. underscores that Federal laws help protect infants from discrimination in the provision of medical treatment, including infants with disabilities. However, the order makes clear that some hospitals still refuse to provide extremely premature (born alive before 24 weeks of gestation) or disabled infants with the mandatory screening, examination, and stabilizing treatment, or potentially lifesaving medical treatment, even when parents plead for such medical care. The E.O. explains that hospitals may be denying “treatment because they believe these infants may not survive, may have to live with long-term disabilities, or may have a quality-of-life deemed to be inadequate.”² The E.O. also explains that denial of lifesaving care or discouragement of parents from seeking such care, “devalues the lives of these children and may violate Federal law.”³ Additionally, the order emphasizes that “infants are entitled to meaningful and non-discriminatory access to medical examination and services, with the consent of a parent or guardian, when they present at hospitals receiving Federal funds.” Among other things, the E.O. directs the Secretary of Health and Human Services (“Secretary”) to:

¹ 85 FR 62187 (Oct. 2, 2020) (“E.O.”).

² *Id.*

³ *Id.*

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- Ensure that individuals responsible for federally funded programs and activities are aware of the obligations they have under the law, including situations when infants are born prematurely or with disabilities.
- Ensure that individuals responsible for federally funded programs and activities are aware that they may not unlawfully discourage parents from seeking medical treatment for their infant child solely because of their infant child's disability.
- Ensure that institutions to which EMTALA applies are aware of their obligations to provide an appropriate medical screening examination and such treatment as may be required to stabilize the individual including infants who are born extremely premature or with disabilities, and obligations for the transfer of such patients to a more suitable facility if appropriate treatment is not possible at the initial location.
- Investigate complaints and take any appropriate enforcement action against individuals or entities found through investigations to have violated Federal law, and clarify the process by which parents and hospital staff may submit such complaints.

The E.O. also states that the Secretary "shall as necessary and consistent with applicable law, issue such regulations or guidance as may be necessary to implement

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[the] order.”⁴ For reasons described further below, the Department has found this proposed rule to be necessary and proper.

Section 504 of the Rehabilitation Act of 1973 prohibits discrimination against a qualified individual with a disability in the United States, solely by reason of her or his disability, in programs and activities that receive Federal financial assistance from the Department.⁵ While Section 504 has been a valuable tool to help address disability discrimination in a variety of contexts, there has been a long and persistent history of discrimination among particularly vulnerable populations with disabilities, including infants with disabilities. Based on its experience stretching back to the Department’s “Baby Doe” rulemaking to protect infants in the 1980s,⁶ to more recent complaints

⁴ *Id.*

⁵ Pub. L. 93-112, 87 Stat. 394 (1973); *see also* 45 CFR 84.44.

⁶ *See* 49 FR 1622, 1623-1649 (Jan. 12, 1984), in which the Department catalogs cases of discrimination against infants with disabilities in the provision of life-saving care.

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received by the Department,⁷ news reports,⁸ input from advocates,⁹ and other sources, the Department recognizes the need for greater regulatory clarity with respect to the protection of persons (infants and adults alike) from disability discrimination, particularly concerning decision making and steering on life-saving or life-sustaining care, or on the provision of any item or service for the purpose of causing or assisting in the death of an individual by assisted suicide, euthanasia, or mercy killing. For the purposes of this regulation, the Department draws from the Assisted Suicide Funding Restriction Act, which prohibits the use of federal funds to provide, pay for, or pay for coverage that includes coverage of, “any health care item or service furnished for the purpose of

⁷ Between 2018 and 2020, the Department received complaints alleging that hospitals denied or sought to deny thirteen infants medical treatment. In these cases, hospitals allegedly denied life-saving care to eleven premature infants, and in two of the allegations, hospitals allegedly denied or sought to deny medical treatment for infants with multiple disabilities. (OCR Transaction Numbers 19-331608, 19-335161, 19-339571, 20-378869, 20-383042, 20-385162, 20-397485, 20-368403, and 20-370970). By referencing these cases, the Department is not prejudging the outcome of any investigation or the ultimate merits of any complaint. These cases are cited here to demonstrate that HHS has received recent complaints by people alleging failures to treat newborn infants and infants with disabilities by medical professionals.

⁸ Madeline Osburn, “Mom Of Premature Twins Who Were Left To Die Calls Trump’s Born Alive E.O. ‘A Glimmer Of Hope,’” *The Federalist* (Oct. 8, 2020), available at <https://thefederalist.com/2020/10/08/mom-of-premature-twins-who-were-left-to-die-calls-trumps-born-alive-e-o-a-glimmer-of-hope/>; “Baby Tinslee given 7 days to live after judge denies injunction,” *WFAA* (Jan. 2, 2020), available at <https://www.wfaa.com/article/news/local/baby-tinslee-given-7-days-to-live-after-judge-denies-injunction/287-c3448934-93fe-42a7-9a29-c1f0153d8d99>.

⁹ Letter from American Association of Pro-life Obstetricians & Gynecologists to Alex M. Azar, Secretary, U.S. Department of Health and Human Services (Oct. 24, 2018), on file with OCR; *see also* Letter from American Association of Pro-life Obstetricians & Gynecologists to Kate Goodrich, Chief Medical Officer and Director for Center for Clinical Standards and Quality, Centers for Medicare & Medicaid Services (Dec. 12, 2018) on file with CMS; Brief to the U.S. Department of Health and Human Services Regarding Perivable Birth from Life Legal Defense Foundation (2020), on file with OCR, *also available at* <https://lifelegaldefensefoundation.org/wp-content/uploads/2020/07/Life-Legal-Age-Discrimination-and-Perivable-Birth.pdf>.

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causing, or for the purpose of assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing.”¹⁰ The Department does not intend to prohibit the administration of palliative care that merely increases the chances of death when the purposes of such care are legitimately palliative and not for the purpose of causing or hastening death. The Department, therefore, proposes clarifications through amendment of its existing regulation under Section 504 and Facility Regulations.

The Department further proposes to clarify that individuals protected by EMTALA include infants born alive at any stage of development, consistent with the Born-Alive Infants Protection Act (BAIPA).¹¹ In 1986, Congress enacted EMTALA to ensure public access to emergency services regardless of ability to pay. Section 1867 of the Social Security Act (SSA) imposes specific obligations on Medicare-participating hospitals that offer emergency services to provide an appropriate medical screening examination (MSE) to individuals with emergency medical conditions (EMCs) when they present for care to dedicated emergency departments or other locations on the campus of a hospital covered by EMTALA.¹² Hospitals are then required to provide stabilizing treatment for patients with EMCs.¹³ If a hospital is unable to stabilize a patient within its

¹⁰ 42 U.S.C. 14402(a).

¹¹ EMTALA was passed as part of the Consolidated Omnibus Reconciliation Act of 1985, Pub. L. 99-272, 100 Stat. 82 (1986). *See also* the definitions of “individual,” “person,” and “born alive” at 1 U.S.C. 8, which was added by BAIPA and is applicable to, among other statutes, EMTALA.

¹² 42 U.S.C. 1395dd; 42 CFR 482.13.

¹³ 42 U.S.C. 1395dd(b)(1).

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capability, or if the patient requests, an appropriate transfer must be implemented. CMS has promulgated regulatory provisions implementing EMTALA in Medicare hospitals.¹⁴

In 2002, Congress enacted BAIPA, which clarified that, “in determining the meaning of any Act of Congress, or of any ruling, regulation, or interpretation of the various administrative bureaus and agencies of the United States, the words ‘person,’ ‘human being,’ ‘child,’ and ‘individual’ include every infant member of the species homo sapiens who is born alive at any stage of development.”¹⁵ According to Congressional findings there was credible public testimony, including eyewitness accounts, of “induced-labor” or “live-birth” abortions in which premature infants born alive were allowed to die, sometimes without basic health care such as temperature regulation and adequate nutrition.¹⁶ According to the House Report on BAIPA, Congress responded by enacting BAIPA to firmly establish that premature infants who are “completely expelled or extracted” alive from their mothers’ wombs are persons under Federal law regardless of their prematurity, likelihood of survival, or the circumstances surrounding their birth.¹⁷

In 2005 and again in 2019, CMS issued guidance clarifying that, under the definition of “individual,” added to the U.S. Code through BAIPA, EMTALA protections

¹⁴ 42 CFR 489.24.

¹⁵ 1 U.S.C. 8.

¹⁶ H. Rept. 107-186 – Born-Alive Infants Protection Act of 2001 (Aug. 2, 2001), *available at* <https://www.congress.gov/congressional-report/107th-congress/house-report/186>.

¹⁷ *Id.*

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apply to born-alive infants in applicable circumstances.¹⁸ Sections 1861(e)(1) through (8) of the SSA provide that a hospital participating in the Medicare program must meet certain specified requirements. Section 1861(e)(9) of the SSA specifies that a hospital also must meet such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals furnished services in the institution. Under Section 1820(e)(3) of the SSA, the Secretary has established regulatory requirements that a critical access hospital must meet to participate in Medicare at 42 CFR part 485, subpart F, and these include the Facility Regulations. Section 1905(a) of the SSA provides that Medicaid payments from States may be applied to hospital services. Under regulations at 42 CFR 440.10(a)(3)(iii) and 42 CFR 440.20(a)(3)(ii), hospitals are required to meet the Medicare Facility Regulations in order to participate in Medicaid. CMS published a regulation implementing the Facility Regulations provisions in the SSA at 42 CFR Part 482. The Department proposes to clarify and specify in that regulation that infants born alive are patients with rights referred to in the Facility Regulations. Further, the Department proposes clarifications to ensure that hospitals are aware that longstanding protections against disability discrimination apply to considerations of whether a treatment or service is unnecessary or inappropriate for a patient (including infants born alive at any stage of development, consistent with 1 U.S.C. 8), and prohibiting steering of

¹⁸ See CMS, Memo 05-26 (REVISED) – EMTALA, “Interaction of the Emergency Medical Treatment and Labor Act (EMTALA) and the Born-Alive Infants Protection Act of 2002.”

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persons with disabilities away from life-saving or life-sustaining care, or towards life-ending items or services, consistent with the proposed amendments with regard to steering under the Section 504 regulations.

B. Section 504 of the Rehabilitation Act of 1973

Section 504 and the Department's implementing regulation at 45 CFR Part 84 prohibit discrimination on the basis of disability in programs and activities that receive Federal financial assistance from the Department. Specifically, Section 504 states that "no otherwise qualified individual with a disability...shall, solely by reason of her or his disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination" in programs or activities that are recipients of Federal funds or that are conducted by Executive agencies or the United States Postal Service.¹⁹

As detailed further in this document, the Department recognizes a long and persistent history of discrimination among people (infants and adults like) with disabilities, in situations regarding the provision or withdrawal of life-saving or life-sustaining care and related pressure from providers covered by Section 504.

Thirty-five years ago, the Department revised its regulation implementing Section 504 after it was reported that hospitals were denying infants with disabilities²⁰ (such as

¹⁹ 29 U.S.C. 794

²⁰ The Department's regulation implementing Section 504, at 45 CFR Part 84, still refers to persons with disabilities as "handicapped" persons. This notice of proposed rulemaking refers to persons with disabilities, but treats the terms as having the same legal meaning.

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Down syndrome) hydration and nutrition until death. Additionally, hospitals refused to address treatable but fatal conditions because of infants' disabilities.²¹ The revised regulation added a requirement that federally funded providers of health care services post a notice informing medical personnel about the civil rights of infants with disabilities, and required that state agencies take certain regulatory or enforcement steps ensuring that health care entities under their jurisdiction did not engage in discrimination against such infants. The Department's 1984 Final Rule was challenged in litigation brought by national hospital and medical associations which argued against liability under Section 504 regulations in cases where parents did not consent to life-saving treatment for their infants with disabilities and the infants' health providers, consistent with the parents' decisions, did not provide the treatment.²² The District Court litigation resulted in a partial injunction of the rule with respect to the rule's application to "newborn infants."²³ On appeal, the Supreme Court subsequently ruled that the regulation was not authorized by Section 504, but the plurality of the Court construed the relevant injunction to *not* encompass cases where parents or guardians consent to a newborn

²¹ 49 FR 1622 (Jan. 12, 1984) (adding 45 CFR 84.55 to HHS's Section 504 regulation).

²² *Am. Hosp. Ass'n v. Heckler*, 585 F. Supp. 541 (S.D.N.Y. May 11, 1984).

²³ Thereafter, HHS issued a Federal Register notice stating that the mandatory provisions in 45 CFR 84.55(b)-(e) are subject to an injunction prohibiting their enforcement, but did not address the situation with respect to instances where parents or guardians consent to treatment of newborn infants with disabilities. 49 FR 1622 (Jan. 12, 1984).

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infant’s treatment.²⁴ Accordingly, this proposed rulemaking is consistent with the plurality’s formulation and regulates discrimination against “newborn infants”²⁵ with disabilities under Section 504 in cases where parents or guardians consent to treatment of their newborn infants, or would otherwise consent to treatment absent steering or undue influence on the basis of disability.²⁶

The Department recognizes that greater clarity is needed under Section 504 regulations concerning discrimination regarding life-saving or life-sustaining services and life-ending items or services. Consistent with Section 504’s prohibition of discrimination on the basis of disability, the Department proposes to clarify that protections under Section 504 apply to discriminatory withdrawal or withholding of requested life-saving or life-sustaining care of individuals with disabilities for adults and infants alike, and to prohibit undue influence or steering of individuals toward the withdrawal of life-saving

²⁴ *Bowen v. Am. Hosp. Ass’n*, 476 U.S. 610, 625 n.11 (1986) (plurality opinion).

²⁵ The Centers for Disease Control and Prevention (CDC) refer to “neonates” (*i.e.* newborns) as infants aged 0-27 days. Infant Mortality Dashboard, CDC-National Center for Health Statistics, *available at* <https://www.cdc.gov/nchs/nvss/vsrr/infant-mortality-dashboard.htm>. For the purposes of this regulation, “newborn infants” means infants aged 0-27 days. Where “infants” appears without the “newborn” qualifier in this proposed regulation or preamble, the broader understanding of “infant,” meaning from 0 to 27 days *and beyond*, applies.

²⁶ Under *Marks v. United States*, when a plurality of the Supreme Court decides a case, the holding “may be viewed as that position taken by those Members who concurred in the judgments on the narrowest grounds.” 430 U.S. 188, 194 (1977). Here, the narrowest ground put forth by the divided court is the position in footnote 11 of the *Bowen* opinion which construed the lower court injunction to not encompass cases where parents or guardians consent to an infant’s treatment. This ground is clearly narrower than interpreting the injunction to bar consideration under Section 504 of all cases of denials of care involving newborn infants with disabilities, regardless of the presence or absence of parental or guardian consent.

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or life-sustaining care, or toward the provision of life-ending services, on the basis of disability.

C. EMTALA

EMTALA requires certain screening and stabilization of patients who come to dedicated emergency departments, or other locations on the campus of a hospital covered by EMTALA. CMS regulations governing hospitals require that covered hospitals provide an appropriate medical screening within the capability of the hospital's emergency department, and if an emergency medical condition is determined to exist, provide any necessary stabilizing treatment.²⁷

D. Conditions of Participation for Hospitals and Critical Access Hospitals

The Facility Regulations currently include provisions known as “conditions of participation” that require hospitals to inform each patient, or when appropriate, the patient's representative, of the patient's rights, in advance of discontinuing patient care, and that such rights include the right to participate in the development and implementation of the patient's plan of care and treatment, the right to make informed decisions regarding the patient's care, the right to be informed of his or her health status, and the right to request treatment.²⁸

E. Summary of the Proposed Rule

²⁷ 42 CFR 489.24(a).

²⁸ 42 CFR 482.13(a)-(b).

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As discussed in greater detail below, this rule proposes to articulate more clearly that, in the context of medical care, Section 504 and its implementing regulations, EMTALA, and CMS Facility Regulations protect infants born alive at any stage of development from disability discrimination to the same extent the provisions would apply with respect to any other individual with a disability, and that Section 504 precludes the denial of care to newborn infants with disabilities whose parents or guardians consent to treatment.

The rule would also clarify that the protections against discrimination for individuals (adults and infants alike) with disabilities apply to decisions to withdraw life-saving or life-sustaining care on the basis of evaluations of the relative worth of life based on disability, or a contention or assessment that an individual does or would impose a burden on caregivers or society based on disability, or on illegal stereotypes or bias based on disability, whether assessed based on the individual's status prior to receiving life-saving or life-sustaining care or anticipated status after receiving life-saving or life-sustaining care.

The rule would clarify that conditions or symptoms constituting or regarded as disabilities (including prematurity) may only be considered as factors in deeming that a life-saving or life-sustaining treatment or service is futile, unnecessary, or inappropriate for an individual if the provider makes an individualized assessment of the relevance of such conditions or symptoms to the individual's short-term survivability and considers

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available auxiliary aids and services and reasonable modifications for alleviating or mitigating such conditions or symptoms. Likewise, the rule would specify criteria that hospitals shall not use as a basis for determining a treatment or service unnecessary or inappropriate.

Further, the rule would assert in Section 504 and Facility Regulations that these protections include a prohibition on covered entities' steering, encouraging, pressuring, or unduly influencing an individual, or his or her legal representative, including a parent or guardian of an infant with a disability, on the basis of discriminatory factors specified in the regulation, to decline or withhold consent for the provision of life-saving or life-sustaining care; to consent to the withdrawal of life-saving or life-sustaining care; or to consent to the provision or receipt of any life-ending item or service (*i.e.*, assisted suicide, euthanasia, or mercy killing). The Department strongly believes that patients and their legal representatives must receive the complete information necessary to make informed decisions about their care, and seeks comment about how covered entities can provide complete information without steering patients in a discriminatory manner described in the rule. The Department does not intend to prohibit the administration of palliative care that merely increases the chances of death when the purposes of such care are legitimately palliative and not for the purpose of causing or hastening death.

The rule also proposes to eliminate enjoined and inoperative provisions at 45 CFR 84.55(b)-(e), redesignate the existing paragraph (a) as paragraph (d), redesignate the

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existing paragraph (f) as paragraph (e), and replace paragraphs (a), (b), and (c) with the content described above and below.

In the CMS EMTALA regulations governing Medicare hospitals, this rule proposes to clarify that infants born alive are encompassed by the term “individuals” under the regulation, consistent with the statutory definition of that term.²⁹

Finally, this rule proposes to clarify patient's protections under CMS Facility Regulations regarding “do not resuscitate orders”. Under current Facility Regulations, hospitals must notify each patient or patient's representative in advance of furnishing or discontinuing care whenever possible. This rule would clarify that this requirement includes informing the patient or the patient’s legal representative (including infants born alive at any stage of development, consistent with 1 U.S.C. 8) if and when a “do not resuscitate order” is entered for the patient when the order was not requested by the patient or the patient’s legal representative. This rule would also clarify that conditions or symptoms constituting or regarded as a disability, including prematurity,³⁰ may only be

²⁹ See 1 U.S.C. 8.

³⁰ Prematurity is correlated with disability depending on the degree of prematurity. See, e.g., Kline, J.E. et al., Retinopathy of Prematurity and Bronchopulmonary Dysplasia are Independent Antecedents of Cortical Maturational Abnormalities in Very Preterm Infants, 9 *Sci. Reps.* 19679 (2019), available at <https://www.nature.com/articles/s41598-019-56298-x> (“Infants born very preterm, at less than 31 weeks gestational age (GA), often develop [neurodevelopmental impairments] such as cognitive, behavioral, and psychological abnormalities. Many also develop motor impairments, including the 10% who develop cerebral palsy”). Infants born prematurely will meet the definition of a qualified individual with disability if they have physical or mental impairment that substantially limits one or more major life activities. See Americans with Disabilities Act (ADA) at 42 U.S.C. 12102(1); 28 CFR 35108(a).

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considered as factors in determining whether a treatment or service is futile, unnecessary or inappropriate for a patient (including an infant born alive) if the hospital makes an individualized assessment of the relevance of such conditions or symptoms to the treatment or service and considering the availability of auxiliary aids and services and reasonable modifications. Likewise, as under the Section 504 proposed amendments, the proposed rule would specify criteria that hospitals are prohibited from using as a basis for determining a treatment or service is unnecessary or inappropriate and would add a provision prohibiting certain steering or pressuring of persons with disabilities regarding life-saving treatment options or life-ending services.

F. Cost-effectiveness of the Proposed Rule

As discussed further below, the full anticipated monetary costs and savings of this proposed rule are not known with confidence at this time and the Department therefore invites members of the public to comment on any aspect of the benefits or costs of this proposed regulation. After the final rule is issued, the Office for Civil Rights (OCR) would provide guidance, training, and technical assistance to covered entities and organizations serving or advocating for members of the public protected by the regulation. In addition, to the extent that the rule clarifies certain authorities, OCR may receive a moderate increase in complaints under the revised regulation,³¹ estimated to be

³¹ See footnote 8 above detailing that between 2018 and 2020, the Department received several complaints alleging that hospitals denied or sought to deny thirteen infants medical treatment.

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in the dozens on an annual basis. However, the rule could also result in a decrease in complaints as entities are more aware of OCR's jurisdictional limits. OCR anticipates any increase in enforcement costs can be met with current resources.

II. Reasons for the Proposed Rulemaking

A. Infants with Disabilities

In recent years, OCR has received several complaints from parents, guardians, or others alleging that a hospital or facility did not provide requested treatment to an infant or infants with disabilities because of discrimination on the basis of disability, in violation of Section 504.³² Additionally, cases of infants with disabilities who are denied life-saving or life-sustaining care continue to garner national media attention,³³ and such cases have resulted in litigation.³⁴

OCR and CMS have reason to believe some hospitals fail to perform the required medical screening and, thus, do not provide potentially life-saving or life-sustaining medical treatment to infants with disabilities or infants born before 24 weeks gestation, even when parents plead for such treatment. For instance, in May 2020, CMS determined

³² See footnote 7 above discussing complaints received.

³³ "Hospital Efforts to Save Very Premature Babies Vary Widely," *Associated Press* (May 7, 2015).

³⁴ See *T.L. v. Cook Children's Med. Ctr.*, 607 S.W.3d 9 (Tex. App. Fort Worth 2020); *Fonseca v. Smith*, No. 2:16-cv-00889-KJM-EFB, 2017 WL 4237865 (E.D. Cal. Sept. 25, 2017), *aff'd*, 827 F. App'x 685 (9th Cir. 2020); *In re Baby "K"*, 16 F.3d 590 (4th Cir. 1994); *Nguyen v. Sacred Heart Med. Ctr.*, 987 P.2d 634 (Wash. App. 1999).

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that an Ohio hospital had failed to meet its obligation under EMTALA to ensure medical screening examinations were performed on twin boys born prematurely (at 22 weeks gestation) in 2017.³⁵ The hospital did not send the twins to its neonatal intensive care unit and the brothers died within several hours after delivery. OCR is considering the civil rights implications of this case and other similar cases. In particular, OCR is concerned that recipients of Federal financial assistance may not be fully aware of their statutory obligations with respect to the civil, EMTALA, and Facility Regulations rights of patients in this context, as well as the Facility Regulations obligations of hospitals, and that the attention that results from this rulemaking will provide an effective and long-lasting solution.

A 2015 study reported in the *New England Journal of Medicine* detailed wide variation in outcomes for infant health based on hospital practices regarding the provision of life-saving or life-sustaining care to premature infants.³⁶ In the spring of 2020, *The*

³⁵ Letter from Captain Gregory Hann, USPHS, Acting Division Director, CMS-Chicago, Survey and Operations Group, to Riverside Methodist Hospital (May 19, 2020), determination letter on file with CMS. Video of events after the birth in question may be found at: *Ohio Hospital Refuses to Help Viable Born Babies*, Created Equal Films (May 23, 2018), available at <https://www.youtube.com/watch?v=tluBozwsk6c&feature=youtu.be>. See also Lisa Bourne, “U.S. hospital refuses to help premature twins born alive, leaves them to die,” *Lifesite News* (May 23, 2018), available at <https://www.lifesitenews.com/news/u.s.-hospital-refuses-to-help-premature-twins-born-alive-leaves-them-to-die>.

³⁶ Matthew A. Rysavy *et al.*, “Between-Hospital Variation in Treatment and Outcomes in Extremely Preterm Infants,” 372 *New England J. Med.* 1801-1811 (May 7, 2015), available at <https://www.nejm.org/doi/full/10.1056/NEJMoa1410689>; See also Patrick J. Marmion, “Refusing to Examine Extremely Premature Newborns,” 85 *The Linacre Quarterly*, no. 1, 9-10 (2018), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6027110/pdf/10.1177.0024363918756390.pdf> (arguing

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New York Times reported about the story of Sarah Kil, a Texas mother, who upon arriving at the hospital in preterm labor said she was told that the hospital would not consider administering life-saving treatment until her unborn baby reached the first day of 23 weeks gestation.³⁷ According to the article, the nurse practitioner told Ms. Kil that “if they did try to save him, he wouldn’t have any quality of life.”³⁸ A day after being in the hospital, Ms. Kil was able to find another hospital (about 15 miles away) that would provide life-sustaining care when her child was born. At 22 weeks and three days, Ms. Kil gave birth to her son who is now a healthy toddler. These cases and the medical literature support the conclusion that active medical intervention for premature infants, even those as young as 22 weeks, can result in recovery and hospital discharge for many infants.³⁹

B. Medical Futility, Quality of Life Judgments, and Persons with Disabilities

Issues surrounding life-saving or life-sustaining care, in particular judgments of medical futility for individuals (infants and adults alike) with disabilities, implicate important civil rights and must be assessed with close attention to the non-discrimination

that the presence of a doctor at all premature births has the potential to save the lives of infants and comfort parents that “all means were taken to save their babies”).

³⁷ Sarah DiGregorio, “Parents of Extremely Premature Babies Face an Impossible Choice,” *The New York Times* (April 16, 2020), available at <https://www.nytimes.com/2020/04/16/parenting/baby/extremely-premature-infants.html>.

³⁸ *Id.*

³⁹ Patricia L. Watkins *et al.*, “Outcomes at 18 to 22 Months of Corrected Age for Infants Born at 22 to 25 Weeks of Gestation in a Center Practicing Active Management,” 217 *J Pediatr.* 52-58 (Feb. 2020), available at <https://pubmed.ncbi.nlm.nih.gov/31606151/>.

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requirements of Federal disability rights law. Evidence from stakeholders, researchers, and advocates shows that people with disabilities face significant discrimination in the provision or withdrawal of life-saving or life-sustaining care, and that there is often confusion on the part of providers about their obligations under Section 504.

The risks of disability discrimination in the context of life-saving or life-sustaining care have come to the forefront during the COVID-19 pandemic. In December 2020, a coalition led by the National Academy of Medicine and the American Medical Association released a joint statement on Crisis Standards of Care (CSC), advising medical providers on how to avoid disability discrimination in medical assessments when triaging life-saving care during emergencies or resource shortages.⁴⁰ The coalition paid particular attention to the criteria used in medical assessments and recommended that hospitals and health care systems allocate resources “based on individualized assessments of each patient, using the best available objective medical evidence”⁴¹ The coalition discouraged the use of discriminatory criteria in decision making, saying that “assessments should NOT use categorical exclusion criteria on the basis of disability or age; judgments as to long-term life expectancy; evaluations of the relative worth of life,

⁴⁰ National Academy of Medicine and American Medical Association *et al.*, “National Organizations Call for Action to Implement Crisis Standards of Care During COVID-19 Surge” (Dec. 18, 2020) (“NAM/AMA Coalition Letter”), available at <https://nam.edu/national-organizations-call-for-action-to-implement-crisis-standards-of-care-during-covid-19-surge/>.

⁴¹ *Id.*

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including through quality of life judgments...” The coalition expanded on possible discriminatory criteria, saying that hospitals’ assessments “should NOT deprioritize persons on the basis of disability or age because they may consume more treatment resources or require auxiliary aids or supports.”⁴²

A report from the National Council on Disability (NCD), *Medical Futility and Disability Bias: Part of the Bioethics and Disability Series*, examined the issue of medical futility determinations and found that decisions by health care providers to withhold or withdraw life-saving or life-sustaining care for people with disabilities are often driven by subjective quality-of-life judgments that may violate Federal disability rights law.⁴³

Medical futility determinations allow physicians and hospitals to discontinue – or not provide in the first place – medical treatment that a patient or his or her legal representative wants when, in the medical professional’s opinion, the treatment would do little or nothing to benefit the patient. Futility policies articulate how hospitals and other health care institutions address such conflicts between physicians and patients (or their families) as to the advisability of continuing what a clinician deems to be “futile care.”

A determination of futility may allow for the withdrawal or withholding of life-saving or life-sustaining treatment over the objection of an individual or his or her family.

⁴² *Id.*

⁴³ National Council on Disability, *Medical Futility and Disability Bias: Part of the Bioethics and Disability Series* (Nov. 2019), 9, 20, 24, 32, available at https://ncd.gov/sites/default/files/NCD_Medical_Futility_Report_508.pdf.

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This area is, accordingly, highly contentious. This issue also presents a significant risk of discrimination for people with disabilities. Futility determinations are typically made in one of two categories:

- a) Determinations of *quantitative futility*, under which a treatment is considered overwhelmingly unlikely to offer any clinical benefit.
- b) Determinations of *qualitative futility*, under which a treatment is considered likely to offer clinical benefit, but the patient's anticipated quality of life after treatment is considered too low to justify the treatment.

The Department believes that qualitative futility determinations on the basis of disability status may constitute disability discrimination under Section 504 and violate patient's rights under the Facility Regulations. Descriptions of qualitative futility determinations in the medical literature sometimes incorporate factors that are discriminatory. For example, in 1990, Dr. Lawrence J. Schneiderman and his colleagues proposed an approach to qualitative futility in the *Annals of Internal Medicine*, stating, in part:

Some qualitatively poor results should indeed be the patient's option, and the patient should know that they may be attainable. We believe, however, that other sorts of qualitatively poor results fall outside the range of the patient's autonomy and need not be offered as options.... Qualitatively poor results [include]... conditions requiring constant monitoring, ventilatory support, and intensive care nursing....⁴⁴

⁴⁴ Lawrence J. Schneiderman, Nancy S. Jecker, and Albert R. Jonsen, "Medical Futility: Its Meaning and Ethical Implications," 112 *Annals of Internal Medicine*, 949-954 (June 1990), available at <https://doi.org/10.7326/0003-4819-112-12-949>.

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By refusing to offer medically useful treatments based solely on the possibility or probability of the patient having a permanent disabling condition, the authors proposed a form of disability discrimination by definition. Likewise, the authors proposed that if a treatment “cannot end dependence on intensive medical care, the treatment should be considered futile.”⁴⁵

Many people with disabilities require the supports described above, often on a long-term basis, in order to survive and thrive. With such supports, people with disabilities, including infants, can live many years, enjoying meaningful social, family, and professional relationships. Physician or hospital denial or withdrawal of life-saving or life-sustaining care, when contrary to the wishes of an individual or his or her legal representative, or the parent or guardian of infants, may constitute unlawful discrimination under Section 504 and violate the patient’s rights under the Facility Regulations if based on a determination that the life of an individual with a disability is not worth living or the individual is effectively “better off dead” because of his or her disability—including on the basis of the individual’s need for ongoing medical care needs, including monitoring, ventilator support, intensive care nursing, as well chronic pain, or other assessment of poor long-term quality of life.

⁴⁵ *Id.*

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One of the previously cited stories concerns an infant with a disability whose case garnered national attention when her hospital and treating physicians acknowledged that, “without life-sustaining treatment, her condition is fatal,” but nevertheless sought to remove life-sustaining treatment because the physicians felt, contrary to the mother’s stated position, that “it is in her best interest to free her from artificial, medical intervention and suffering.”⁴⁶

NCD and non-government stakeholders working on disability rights have shared the Department’s concerns about disability discrimination and medical futility policies. NCD concluded that health care providers who are called upon to make decisions about medical futility are often impacted by their own views regarding the quality of life of individuals with disabilities, which may depart significantly from the views of people with disabilities themselves.⁴⁷ On May 6, 2019, a coalition of 17 leading organizations that advocate for, or serve, individuals with disabilities wrote to OCR to raise concerns about “the often-discriminatory practice of medicine” related to “so-called ‘futile care’

⁴⁶ *Cook Children’s Statement Regarding Patient Tinslee Lewis* (Nov. 10, 2019) reprinted at <https://wingright.orgwww.wfaa.com/article/news/health/9-month-old-baby-to-be-taken-off-life-support-sunday-against-mothers-wishes-advocacy-group-says/287-40975c35-8ce5-4f35-8441-2aa9bf21b66d>; See also Madeline Holcombe, “Judge orders a hospital to keep 9-month-old on life-support as her family searches for a solution,” *CNN* (Nov. 13, 2019), available at <https://www.cnn.com/2019/11/11/cooks-childrens-press-release-on-tinslee-lewis/>. 13/us/texas-infant-life-support-restraining-order/index.html. The mother was not the legal representative for her child’s medical decision making at the time, but has since engaged in litigation that has succeeded in keeping her child alive well past her one-year birthday. *T.L.*, 607 S.W.3d 9.

⁴⁷ National Council on Disability, *Medical Futility and Disability Bias*, 28-32.

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laws and policies, which allow doctors to deny life-sustaining treatment to people with disabilities who want and need it.”⁴⁸

In addition to inappropriate assessments and denials or withdrawals of care, the Department is concerned by the possibility of inappropriate steering of individuals or their legal representatives, including parents or guardians of infants with disabilities, to decline life-saving or life-sustaining care or to consent to the withdrawal of life-saving or life-sustaining care once provided. The impropriety of such pressure is exacerbated by the power differential that exists when individuals with disabilities, parents, and guardians are called to make profound and permanent decisions, often on an urgent basis, at the behest of highly specialized physicians who can effectively use their credentials or authority to apply pressure even against the patient’s known desires.

Disability organizations have raised particular concerns about discrimination and pressuring of individuals with disabilities with respect to the provision of or referral for life-ending services. In its report, *The Danger of Assisted Suicide Laws*, NCD found that individuals with disabilities have been steered to end their lives when faced with life-

⁴⁸ Letter from a coalition of 17 organizations to Roger Severino, Director, Office for Civil Rights (May 6, 2019). The coalition, which represents millions of persons, also criticized discrimination against persons with disabilities in organ transplantation and assisted suicide. This letter and its arguments have also been taken into account by the Department in reaching its proposed prohibition of steering of persons with disabilities towards assisted suicide or euthanasia on the basis of disability. The letter will be included in the docket of this proposed rule as supplemental material at www.regulations.gov.

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threatening conditions, even if the conditions are eminently treatable.⁴⁹ NCD argues that when assisted suicide is legal, it often becomes the cheapest treatment, and cites two cases where individuals with disabilities were denied certain treatments by insurers though assisted suicide remained a covered option.⁵⁰ Other advocacy groups and academic literature argue that persons with disabilities are particularly targeted for steering and pressure towards euthanasia or assisted suicide because of discrimination or biases about living with disabilities.⁵¹ The Department is concerned that similar steering may occur encouraging individuals with disabilities or their guardians to consent to the receipt or provision of any life-ending item or service, including for infants with disabilities.

In January 2019, the Governor of Virginia, a pediatric neurologist, described a practice in which newborn infants with disabilities are potentially discriminated against on the basis of their disability:

When we talk about third trimester abortions, these are done with the consent of, obviously the mother with the consent of the physicians, more than one physician, by the way, and it's done in cases where there may be severe deformities, there may be a fetus that's not viable. So in this particular example, if a mother is in

⁴⁹ National Council on Disability, *The Danger of Assisted Suicide Laws: Part of the Bioethics and Disability Series* (Oct. 2019), 20, available at https://ncd.gov/sites/default/files/NCD_Assisted_Suicide_Report_508.pdf.

⁵⁰ *Id.* at 20.

⁵¹ See, e.g., Patients' Rights Action Fund and Disability Rights Education and Defense Fund, "A Primer on Assisted Suicide Laws," available at <https://patientsrightsaction.org/wp-content/uploads/2017/07/Final-Primer.pdf>; "Killing us softly: the dangers of legalizing assisted suicide," 3 *Disability and Health Journal* 16-30 (2010), available at <https://dredf.org/wp-content/uploads/2012/08/PIIS1.pdf>.

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labor I can tell you exactly what would happen. The infant would be delivered; the infant would be kept comfortable; the infant would be resuscitated if that's what the mother and family desired, and then a discussion would ensue between the physicians and the mother.⁵²

The Department is concerned that such a “discussion” may include discriminatory steering towards euthanasia or the withholding or withdrawal of life-saving or life-sustaining care on the basis of disability. Under the proposed regulation, such steering or pressure for adults and newborn infants alike would be prohibited.

The Department seeks additional comments on the extent of the problem in the medical community as a whole with respect to infants, minors, and adults with disabilities.

III. Proposed Rule

This proposed rule would amend the existing regulation at 45 CFR Part 84, prohibiting disability discrimination in programs and activities that receive Federal financial assistance from HHS. It would also amend HHS's Facility Regulations and EMTALA regulations at 42 CFR Parts 482 and 489.

The proposed amendments to 45 CFR Part 84 would:

⁵² Hallie Mellendorf, “Va. Gov. Northam draws outrage from GOP for defending abortion bill,” *WTOP* (Jan. 31, 2019), available at <https://wtop.com/local-politics-elections-news/2019/01/va-gov-northam-draws-outrage-from-gop-for-defending-abortion-bill/>.

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- (a) eliminate provisions enjoined by a district court (§§ 84.55(b)-(e)) and accompanying notes;
- (b) redesignate the existing paragraph (a) as paragraph (e);
- (c) add new paragraphs § 84.55(a), (b), (c), and (d) indicating that protections against discrimination:
 - (1) apply to infants born alive, and with respect to treatment, to newborn infants with, having a record of, or regarded as having, disabilities where the parents or guardians seek, or consent to, treatment for the newborn infants;
 - (2) apply to decisions to provide or withdraw life-saving or life-sustaining care on the basis of certain quality of life or burden evaluations, or stereotypes or bias, based on disability;
 - (3) specify that conditions or symptoms constituting or regarded as disabilities (including prematurity) may only be considered as factors in determining whether a life-saving or life-sustaining treatment or service is futile, unnecessary, or inappropriate if the provider makes an individualized assessment of conditions relevant to short term survival, including availability of auxiliary aids, supports, and reasonable modifications, and prohibit providers from determining that such treatment is futile, unnecessary, or inappropriate on the basis of specified discriminatory factors;
 - (4) prohibit steering, encouraging, pressuring, or unduly influencing an individual with a disability or his or her legal representatives, including a parent or guardian of an

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infant with a disability, to decline or withhold consent for life-saving or life-sustaining care, to consent to the withdrawal of such care or to the provision of any life-ending item or service such as by assisted suicide, euthanasia, or mercy killing, on the basis of specified discriminatory factors.

The proposed rule would also modify CMS's EMTALA regulations at 42 CFR 489.24 to clarify that individuals protected by that rule, consistent with 1 U.S.C. 8, include infants born alive.

The proposed rule would also modify CMS's existing Facility Regulations at 42 CFR 482.13 to clarify that individuals protected by the Patient's Rights Facility Regulations include infants born alive and to specify in section 482.13(b)(2) that conditions or symptoms constituting or regarded as disabilities (including prematurity) may only be considered as factors in deeming a treatment or service futile, unnecessary, or inappropriate for a patient if the provider makes an individualized assessment relevant to the treatment or service and considers the availability of auxiliary aids and services and reasonable modifications, and that hospitals shall not deem a treatment unnecessary or inappropriate based on an assessment of the relative worth of life of a patient or on stereotypes or bias based on disability, including prematurity. Finally, through the addition of new paragraph (b)(5), the proposed Facility Regulations changes would, consistent with the proposed changes to the Section 504 regulation, prohibit steering of an individual with a disability, his or her legal representatives, or parent or guardian of an

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infant, away from life-saving or life-sustaining care, or towards life-ending services on the basis of disability.

A. 45 CFR 84.55 Infants with Disabilities

In response to the injunction of the Department’s “Baby Doe” regulations in the 1980s (discussed above), the Department appended a note to 45 CFR 84.55 stating that a court had enjoined the mandatory provisions of 45 CFR 84.55(b)-(e), which provide for notice requirements, obligations of child protective service agencies, and expedited access to records and enforcement with respect to a provider’s treatment of infants with disabilities.⁵³ In order to eliminate any potential confusion, the Department considers it appropriate to propose to “clean up” and delete the enjoined paragraphs from the rule because they have not been in effect for several decades and also to remove the accompanying explanatory note.

The Department proposes to insert a new paragraph (a) stating that the provisions of part 84 apply to the treatment or service of infants with disabilities (or, as used elsewhere in that part, “handicapped infants”), including infants born alive at any stage of development, consistent with 1 U.S.C. 8, to the same extent the provisions would apply with respect to any other individual with, with a record of, or regarded as having, a

⁵³ 52 FR 3011, 3012 (Jan. 30, 1987).

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disability,⁵⁴ and, in the case of treatment of a newborn infant, where the newborn infant's parent or legal representative with legal authority consents to the treatment or service.

This provision would clarify that the provisions of this part apply to infants born alive at any stage of development, consistent with 1 U.S.C. 8, which defines the words "person," "human being," "child," and "individual" to "include every infant member of the species homo sapiens who is born alive at any stage of development." This rule would not preclude the use of well-established standards of quantitative medical futility applied equally across the lifespan and equally to people with and without disabilities.

The Department further considers it appropriate to clarify with this proposed new paragraph (a) that, consistent with the Supreme Court's plurality decision in *Bowen v. American Hospital Association*,⁵⁵ newborn infants with or regarded as having disabilities are entitled to full protection from discrimination with respect to treatment, where the newborn infants' parents or guardians seek or consent to the treatment or service. This is also consistent with Executive Order 13952, which states that infants and newborns with disabilities "are entitled to meaningful and non-discriminatory access to medical

⁵⁴ This construction parallels the definition of an individual with a disability under Section 504, which includes any person who has a physical or mental impairment which substantially limits one or more major life activities, has a record of such an impairment, or is regarded as having such an impairment. This construction or formulation is also reflected in HHS's existing 504 regulation at 45 CFR 84.3(j)(1), which defines "handicapped person."

⁵⁵ 476 U.S. 610 (1986).

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examination and services, with the consent of a parent or guardian, when they present at hospitals receiving Federal funds.”⁵⁶

Under the proposed new paragraph, if, for example, the parents of a newborn infant with Down syndrome consent to surgery to address an atrioventricular septal defect, the Section 504 regulation would prohibit discrimination on the basis of disability as a ground for denial of such surgery for the newborn infant. Without additional facts, the proposed new paragraph (a) would not be expected to reach cases where a parent or guardian refuses to give consent to treatment.⁵⁷ The Department seeks comment on whether and, if so, how the Department can address cases where the refusal to provide consent for a newborn child with a disability is related to known or suspected abuse or neglect by the parent or guardian withholding consent.

Additionally, the proposed rule would clarify that impermissible discrimination includes denying life-saving or life-sustaining care on the basis of evaluations of the relative worth of the life of an individual with a disability or disabilities compared to a person without the disability or disabilities, or a belief that the patient does or would impose a burden on caregivers or society based on disability, or on stereotypes or bias,

⁵⁶ 85 FR 62187 (Sept. 25, 2020).

⁵⁷ Although the plurality of the Supreme Court in *Bowen* noted that, “a hospital’s selective refusal to report medical neglect of handicapped infants might violate § 504,” it also went on to say that it found no evidence of such a scenario actually occurring, and this proposed rulemaking would impose no additional reporting requirements on this issue on covered entities, to the extent any already exist, 476 U.S. at 637—38.

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based on disability, whether assessed based on the individual's disabilities prior to receiving life-saving or life-sustaining care or anticipated disabilities after receiving life-saving or life-sustaining care.

Consider, for example, parents or legal guardians seeking treatment for a newborn infant with a disability with a respiratory infection where the infant's physician concludes that the newborn will likely require use of a ventilator on a chronic basis in the event that she survives treatment for the infection. Judging chronic ventilator use to be a qualitatively poor outcome, the physician refuses to provide treatment despite a reasonable certainty that such care would prolong the patient's life, because that care is deemed "qualitatively" futile. Because the provider has withheld effective life-saving or life-sustaining care based on a determination regarding quality of life based on disability despite the parent's consenting to or requesting the treatment, under the proposed rule, the provider may have discriminated against the newborn infant on the basis of disability. The same analysis would apply under the proposed rule in cases of adults with disabilities who are denied requested life-saving or life-sustaining care if the denial is based on similarly discriminatory reasons or methods.

The Department also proposes the addition of a new provision that would clarify that conditions or symptoms constituting or regarded as disabilities (including disabilities related to prematurity) may only be considered as factors in deeming a life-saving or life-sustaining treatment or service futile, unnecessary, or inappropriate for an individual if

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the provider makes an individualized assessment of the relevance of such conditions or symptoms to short term survivability and considers the availability of auxiliary aids and services and reasonable modifications.⁵⁸ Here, the Department’s proposed language parallels the recommendations of the National Academy of Medicine and American Medical Association (discussed earlier) concerning life-saving resource allocation during crises—namely, that providers should prioritize resources based on individualized assessments, which “should NOT use categorical exclusion criteria on the basis of disability or age; judgments as to long-term life expectancy;...and should NOT deprioritize persons on the basis of disability or age because they may consume more treatment resources or require auxiliary aids or supports.”⁵⁹

The following example illustrates this point. Consider a provider that adopts a clinical assessment tool for purposes of assessing short-term mortality risk that uses motor and verbal response to assess mortality risk. Autistic patients, patients with cerebral palsy and others with stable underlying disabilities that impact motor and verbal response may require reasonable modifications (such as an exception) to the use of the assessment tool to avoid discrimination on the basis of disability. This is because the

⁵⁸ The language regarding reasonable modifications proposed in this rule is based on Title II of the ADA, as implemented in the Department of Justice’s ADA regulations at 28 CFR 35.130(b)(7). In interpreting Section 504 over many years, the Department has consistently required the provision of reasonable modifications of policies, practices, or procedures when such modifications are necessary to avoid discrimination on the basis of disability, unless the covered provider can demonstrate that making the modifications would fundamentally alter the nature of the health program or activity.

⁵⁹ NAM/AMA Coalition Letter (emphasis in original).

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instrument would increase a patient's assessed mortality risk based on disability-related characteristics that do not actually increase mortality risk. However, the same instrument may be appropriate for use when used in the context of an acute injury or illness where the trendline of changes in motor or verbal response is predictive of mortality risk based on the best available objective medical evidence.

The Department also proposes the addition of a new provision prohibiting covered providers from steering, encouraging, or unduly influencing individuals with disabilities or parents or guardians of infants to decline or withhold consent for the provision of life-saving or life-sustaining care, to consent to the withdrawal of life-saving or life-sustaining care, or to consent to the provision of any life-ending item or service (such as assisted suicide, euthanasia, or mercy killing) on the basis of discriminatory factors, including evaluations of the relative worth of the life of an individual with a disability or disabilities, a belief or assessment that an individual would impose a burden based on disability, or stereotypes or bias based on disability. Again, the National Academy of Medicine and American Medical Association recommendations with respect to Crisis Standards of Care are important reference points in that they recommend providers “[p]lan for how to engage families and palliative care departments in end-of-

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life discussions and, . . . Avoid steering or pressuring patients to agree to the withdrawal or withholding of life-sustaining care.”⁶⁰

In its report, *Medical Futility and Disability Bias*, NCD discusses the example of Terrie Lincoln who, at age 19, was in an automobile accident that severed her spinal cord and caused her to become quadriplegic. The report describes that when Ms. Lincoln “was in the hospital just following her accident, her doctors repeatedly tried to influence her family to ‘pull the plug,’ stating that Ms. Lincoln was a ‘vegetable’ and, even if she were to regain consciousness, would have no quality of life.” When Ms. Lincoln did regain consciousness, she was pressured by her doctors to forego additional medical treatment that would extend her life. Ms. Lincoln persisted, later coming off the ventilator, earning degrees in social work and public administration, and becoming a disability rights advocate and mother.⁶¹ This proposed provision would protect patients and their legal representatives or guardians from such discriminatory pressure, including the parents or guardians of infants with similar disabilities.

The proposed provision would still preserve the ability of providers to provide individuals, their legal representatives, and the parents or guardians of infants with full information on the potential risks and benefits of particular treatments, but would clarify that providers may not use discriminatory reasons related to disability to pressure such

⁶⁰ *Id.*

⁶¹ National Council on Disability, *Medical Futility and Disability Bias* 27 (Nov. 2019).

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individuals to decline treatment, or provide consent for the withdrawal of life-saving or life-sustaining care, or to consent to the provision of items or services administered for the purpose of ending life.

B. 42 CFR 489.24 EMTALA responsibilities in Medicare hospitals

The proposed rule would insert a definition of “individuals” into paragraph (b) of 42 CFR 489.24. The definition would specify that the term individual includes infants born alive at any stage of development, consistent with 1 U.S.C. 8.

With the definition of the terms “person” and “individual” codified at 1 U.S.C. 8, it is clear that there are circumstances where EMTALA protections attach to an infant who is born alive, as that term is defined in 1 U.S.C. 8(b). For example, assume that a hospital’s labor and delivery department meets the definition of a “dedicated emergency department” under the EMTALA regulations. If an infant were born alive (again, as that term is defined in 1 U.S.C. 8(b)) in such a facility, or a request were made on that infant’s behalf for screening for a medical condition (or if a prudent layperson would conclude, based on the infant’s appearance or behavior, that the infant needed examination or treatment for an emergency medical condition and that a request would have been made for screening), the hospital and physician would be liable for violating EMTALA for failure to provide a screening examination under 42 U.S.C. 1395dd(a). Additionally, if the facility determines that the infant has an emergency medical condition, it would be

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liable for violating EMTALA under 42 U.S.C. 1395dd(b) if it fails to provide such further medical examination and such treatment as may be required to stabilize the medical condition, or for transfer to another medical facility. Liability under either case follows because the born-alive infant is a “person” and an “individual” under 1 U.S.C. 8(a), and the screening requirement of EMTALA applies to “any individual” who comes to the emergency department.

Another example could occur were an infant to be born alive elsewhere on the hospital’s campus (*i.e.*, not in the hospital’s dedicated emergency department) and a prudent layperson observer concluded, based on the born-alive infant’s appearance or behavior, that the born-alive infant were experiencing an emergency medical condition. In such a circumstance, a hospital covered by EMTALA and its medical staff would be required to perform a medical screening examination on that born-alive infant to determine whether or not an emergency medical condition existed. If the hospital or its medical staff determined that the born-alive infant were suffering from an emergency medical condition, there would then arise an obligation to admit the infant, or to comply with either the stabilization requirement or the transfer requirement, or risk a finding of an EMTALA violation. Again, this follows because the born-alive infant is a “person” and an “individual,” as described above, and the stabilization and transfer requirements of EMTALA apply to “any individual” who comes to the hospital. The proposed definition

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would serve to clarify, and remind, covered entities of the scope of their EMTALA obligations by codifying in the regulation the statutory definition of “individual.”

C. 42 CFR 482.13 Conditions of Participation for Hospitals and Critical Access Hospitals

This proposed rule would modify 42 CFR 482.13 to clarify, and specify in regulation, that individuals protected by the Patient’s Rights Facility Regulations include infants born alive. The proposed rule also would provide additional clarity regarding the existing requirement to notify each patient or patient’s representative in advance of furnishing or discontinuing care whenever possible. Specifically, the proposed rule would clarify that this requirement includes informing the representative of a patient, including infants born alive, if and when a “do not resuscitate order” is entered when the order was not requested by the patient or the patient’s legal representative. The proposed rule would also clarify that nondiscrimination protections apply in situations where a hospital is considering whether a treatment is medically unnecessary, inappropriate, or futile. Specifically, the proposed rule would clarify that conditions or symptoms constituting or regarded as disabilities, including prematurity, may only be considered as factors in deeming that a treatment or service is unnecessary, inappropriate, or futile for a patient (including an infant born alive) if the hospital makes an individualized assessment of the

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relevance of such conditions or symptoms and considers the availability of auxiliary aids and services and reasonable modifications.⁶²

Furthermore, for the reasons discussed earlier, the Department is concerned that the use of assessments of the relative worth of the life of an infant with a disability or disabilities constitutes discrimination on the basis of disability when used as a basis to provide or withdraw life-saving or life-sustaining care. Accordingly, the proposed rule would specify that hospitals may not base determinations on discriminatory criteria such as the relative worth of the life of a patient (including infants born alive at any stage of development, consistent with 1 U.S.C. 8), or on stereotypes or bias based on disability including prematurity.

IV. Regulatory Impact Analysis

A. Introduction and Summary

The Department has examined the impacts of this proposed rule, as required under E.O. 12866 on Regulatory Planning and Review (Sept. 30, 1993), E.O. 13563 on Improving Regulation and Regulatory Review (Jan. 18, 2011), E.O. 13771 on Reducing Regulation and Controlling Regulatory Costs (Jan. 30, 2017), the Regulatory Flexibility

⁶² In interpreting Section 504 over many years, the Department has consistently required the provision of reasonable modifications of policies, practices, or procedures when such modifications are necessary to avoid discrimination on the basis of disability, unless the covered provider can demonstrate that making the modifications would fundamentally alter the nature of the health program or activity.

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Act (Sept. 19, 1980, Pub. L. 96-354 (codified at 5 U.S.C. 601-612)), sec. 202 of the Unfunded Mandates Reform Act of 1995 (Mar. 22, 1995, Pub. L. 104-04), E.O. 13132 on Federalism (Aug. 4, 1999), Subtitle E of the Small Business Regulatory Enforcement Fairness Act (the Congressional Review Act) (5 U.S.C. 801–808), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

B. Executive Orders 12866 and Related Executive Orders on Regulatory Review

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866, emphasizing the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

Under Executive Order 12866, OMB's Office of Information and Regulatory Affairs (OIRA) determines whether a regulatory action is significant and, therefore, subject to the requirements of Executive Order 12866 and OMB review. Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule that: (1) has an annual effect on the economy of \$100 million or more, or adversely affects in a material way a sector of the economy, productivity, competition,

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jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as economically significant); (2) creates serious inconsistency or otherwise interferes with an action taken or planned by another agency; (3) materially alters the budgetary impacts of entitlement grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raises novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866. This proposed rule has been designated a "significant regulatory action" although not economically significant, under section 3(f) of Executive Order 12866. The Office of Management and Budget has reviewed this proposed rule.

As described above, the Department believes the proposed regulation is necessary to clarify statutory protections against disability discrimination, given complaints the Department has received, news reports, as well as input from advocates, and other sources. Likewise, as described above and below, the Department believes that the approach in the proposed rule is in accordance with the principles re-affirmed by Executive Order 13563.

(1) Examples of Covered Entities

The covered providers most likely to be impacted by the rule are hospitals and clinics. The Department estimates that this regulation will apply to between 2,412 and 3,495 hospitals and clinics across the United States, primarily based on their provision of

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labor and delivery services. The Department solicits comment on the most effective approach for estimating the covered entities impacted by this proposed rule.

(2) *Costs*

If this rule were finalized as proposed, it is expected that hospitals would be called upon to use medically necessary interventions in their neonatal intensive care units to address the needs of infants born before prematurely as well as interventions for adults with disabilities in critical care scenarios that would otherwise not be treated. There are few studies estimating the costs of care for preterm infants in the United States, and the Department invites comment on the costs and benefits.⁶³ Estimating costs for adults is a complicated task given that adults experience a wide variety of health conditions and there is substantial debate surrounding economic evaluations of end of life care.⁶⁴ Likewise, researchers have noted a knowledge gap in studies surrounding supportive end of life care.⁶⁵ According to the 2018 American Hospital Association Annual Survey, the average cost per inpatient day ranged from \$2,260 for state/local government hospitals, \$2,653 for nonprofit hospitals, and \$2,093 in for-profit hospitals.⁶⁶ The Department

⁶³ Compare with Irene Guat Sim Cheah, “Economic assessment of neonatal intensive care,” 8 *Translational pediatrics*, no. 3, 247 (July 2019), available at <https://doi.org/10.21037/tp.2019.07.03>.

⁶⁴ See Philip Kinghorn and Johanna Coast, “Appropriate frameworks for economic evaluation of end of life care: A qualitative investigation with stakeholders,” 33 *Palliative Medicine* 7:823-831 (March 27, 2019), available at <https://doi.org/10.1177/0269216319839635>.

⁶⁵ *Id.*

⁶⁶ Ayla Ellison, “Average hospital expenses per inpatient day across 50 states,” *Becker’s Hospital Review* (Feb. 28, 2020), available at <https://www.beckershospitalreview.com/finance/average-hospital-expenses-per-inpatient-day-across-50-states-02282020.html>.

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solicits comment on the most accurate and appropriate methods for estimating potential costs of this proposed rule on covered entities, including the costs related to medical care or rehabilitation resulting from increased lives saved as a result of this proposed rule.

Although difficult to estimate, based on the number of reported incidents of potentially discriminatory denials of care, the Department estimates that the number of individuals who will receive life-sustaining or life-saving treatment that they would otherwise not have received will be in the double digits annually. The Department solicits comment on this estimate.

Finally, the Department acknowledges that it may incur additional costs related to increased enforcement and investigation costs, but likewise estimates the number of additional cases that may arise from the added public awareness of the rights of individuals with disabilities, including infants, under Section 504, EMTALA, and Facility Regulations to be in the double digits annually for adults and infants combined. To the extent that the proposed rule would clarify certain authorities, the proposed rule could result in an increase in complaints, estimated to be in the double digits annually. However, the proposed rule could also result in a decrease of complaints over time as entities are more aware of their obligations and the parameters of OCR's jurisdiction. OCR anticipates the increase in enforcement costs to have a minor impact on OCR's budgetary needs. The Department solicits comment on the possible costs of this proposed

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rule mentioned herein and any other costs pertaining to individuals with disabilities, including infants, and entities that may be impacted by this proposed rule.

(3) Benefits

Many of the benefits in this area are difficult to quantify or monetize such as furthering the public recognition that all human life is valuable, including all infants born alive. The most important benefit, however, would be the increased survival of adults and children that would otherwise not be provided life-sustaining or life-saving care, which, based on the number of reported incidents of potential improper denials of such care described above, the Department estimates to be in the double digits as a result of increased public awareness flowing from finalization of the proposed rule. It is more difficult to quantify the number of persons whose lives would be saved due to reduced steering or pressuring of patients away from life-saving or life-sustaining care and reduced steering towards life-ending services, and the Department solicits comments on this question. As described above, the Department believes at this time that the number of infants and adults who would receive life-sustaining or life-saving treatment that they would otherwise not have received will be in the double digits annually combined. The Department solicits comment on these estimates and on the benefits to individuals with disabilities, including infants, and their families and the best manner of quantifying the benefit of expected lives saved.

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(4) Alternatives Considered

Three other options available to the Department – leaving in place the current regulations, *e.g.*, doing no rulemaking, eliminating all references to nondiscrimination against infants born alive and infants with disabilities, or requiring broader provision of notice – are suboptimal. Leaving in place all the existing regulatory language, which the Supreme Court has determined to be not authorized by the statute in the case of Section 504, would be misleading and continue the confusion that exists in this area. Eliminating all such regulatory requirements would fail to recognize that part of the Supreme Court’s *Bowen* plurality decision explicitly left in place the rights of infants whose parents seek or consent to treatment, would fail to address the instances of discrimination that have been brought forth to the Department, and would fail to implement E.O. 13952, which requires that the Department engage in necessary rulemaking in this area. Going beyond the proposed rule and imposing a notice requirement on covered hospitals to provide patients receiving labor and delivery services notice of their rights under Section 504 and EMTALA was considered. The Department does not propose to adopt such requirements at this time, but solicits further public comment on this issue. The Department also solicits comment on other potential alternatives to achieve the stated goals of the rulemaking effectively and with minimal regulatory burden.

C. Assessment of Federal Regulation and Policies on Families

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The Department has determined that the proposed rule will positively impact family well-being, in accordance with the principles of Section 654 of the Treasury and General Government Appropriations Act of 1999 (Pub. L. 105-277). The rule would strengthen the rights of parents by recognizing their right to ensure that their children receive the medical treatment they seek or for which they have provided consent and for their children not to be denied medical care for discriminatory reasons. Finally, increased survival of family members, whether infant or adult, positively impacts families.

D. Impact on State, Local, and Tribal Entities under Executive Orders 12866, 13132, and 13175

The Secretary has determined that this proposed rule comports with Executive Order 13132.⁶⁷ This proposed rule would not impose substantial direct effects on States and their political subdivisions, modify the relationship between the Federal government and the States, or alter the distribution of power and responsibilities among the various levels of government.⁶⁸ The Department believes that the proposed rule would not have tribal implications as defined in Executive Order 13175, and that tribal consultation regarding the proposed rule was, therefore, not necessary.

E. Executive Order 13771 on Reducing and Controlling Regulatory Costs

⁶⁷ E.O. 13132, 64 FR 43255 (Aug. 10, 1999).

⁶⁸ E.O. 13132, section 1(a). E.O. 13132 requires an agency to meet certain requirements when it promulgates a rule with “policies that have federalism implications.” *Id.* sections 2-3, 6(b)-(c) (identifying federalism principles, policymaking criteria, and consultation requirements).

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This proposed rule is expected to be an Executive Order 13771 regulatory action.

Preliminary estimates of the costs that would be tallied for Executive Order 13771

purposes are provided above in the discussion of potential costs associated with the rule.

F. Unfunded Mandates Reform Act

The Department has determined that this proposed rule is not likely to result in expenditures by State, local, and tribal governments, or by the private sector, of \$154 million or more in any one year, and is, therefore, not subject to the requirements of Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act). 2 U.S.C. 1532. Furthermore, the proposed rule also falls under an exception for regulations that establish or enforce any statutory rights that prohibit discrimination on the basis of race, color, religion, sex, national origin, age, handicap, or disability. 2 U.S.C. 1503(2).

G. Regulatory Flexibility Act and Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking

The Department has examined the economic implications of this proposed rule under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612). The RFA requires an agency to explain the impact of a proposed regulation on small entities by providing an initial regulatory flexibility analysis unless the agency expects that the proposed rule will not have a significant impact on a substantial number of small entities, provides a factual basis for this determination, and proposes to certify the statement. 5 U.S.C. 603(a),

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605(b). If an agency must provide an initial regulatory flexibility analysis, this analysis must address the consideration of regulatory options that would lessen the economic effect of the rule on small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.

The Department does not anticipate that this proposed rule would have a substantial impact on a substantial number of small entities because the proposed rule is unlikely to meet the threshold of a three percent impact on revenue on at least five percent of small entities. As previously discussed, this proposed rule would require covered providers to comply with applicable Federal statutory nondiscrimination provisions. Affected small entities may include small hospitals that provide emergency treatment for infants. Since the number of extremely premature infants born in a small or nonprofit hospital who meet the criteria for treatment under this proposed rule is likely to be low, the Department has determined, and the Secretary certifies, that this proposed rule will not have a significant impact on the operations of a substantial number of small entities. The Department seeks comment on this analysis of the impact of the proposed rule on small entities, and the assumptions that underlie this analysis.

H. Executive Order 12250 on Leadership and Coordination of Nondiscrimination Laws

Under Executive Order 12250, the U.S. Department of Justice has the responsibility to coordinate the implementation and enforcement by Executive agencies

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of Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794), and other statutes that prohibit discrimination on the ground of race, color, national origin, disability, religion, or sex under any program or activity receiving federal financial assistance. Executive Order 12250 also requires review of proposed regulations implementing laws covered by the order to identify those which are inadequate, unclear or unnecessarily inconsistent. The Department of Justice has reviewed the proposed regulation and, pursuant to Executive Order 12250, has approved the proposed rule.

I. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. ch. 3506; 5 CFR part 1320 appendix A.1), the Department has reviewed this proposed rule and has determined that there are no new collections of information contained therein.

V. Effective Date

The Department proposes that the effective date be 60 days after publication of the Final Rule.

VI. Request for Comment

The Department seeks comment on all issues raised by the proposed regulation and as solicited above. Additionally, the Department requests comment on:

- The scope of the problems discussed in this proposed rule;

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- Whether individuals with disabilities and their legal representatives, including parents or guardians of infants with disabilities, would be adequately informed of their rights and the rights of infants under the proposed rule, and, if not, what should be done to address the issue;
- How to ensure that patients with disabilities, or their legal representatives with legal authority, receive comprehensive information necessary to make informed decisions about their care without violating the prohibition against steering in the rule;
- The potential impact of the Section 504 steering prohibition proposed in this rule on the scope or application of steering prohibitions that may otherwise apply in different contexts or in a different manner under Section 504 or the ADA;
- Other examples of discrimination against individuals with disabilities, including infants, not mentioned elsewhere in this document;
- Impact on families, including the impact on parental rights to direct their children's medical decision making, and informed consent without coercion;
- The impact on the best interest of the child, including infants with disabilities;
- The respective roles of the Federal, State, and local governments with respect to their legal authority or obligation to protect individuals, including infants, from disability discrimination in health care;

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- Whether conflicts of interest such as financial or malpractice mitigation contribute to violations of Federal disability nondiscrimination law with respect to treatment of individuals with disabilities under this proposed regulation, including infants;
- Examples with respect to the provision or withdrawal of life-saving or life-sustaining care where disability discrimination occurs in a manner not described or accounted for in the proposed regulation;
- Examples of steering, encouraging, pressuring, or unduly influencing individuals with disabilities, or a parent or guardian of an individual with a disability, including an infant, to consent to the provision or receipt of any life-ending item or service, such as administration of drugs beyond palliative purposes and for the purpose of causing or hastening death on the basis of disability;
- Whether any undefined terms used in the proposed regulation should be defined as well as proposed definitions for those terms; and
- The benefits and costs associated with this rulemaking.

List of Subjects

42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

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Administrative practice and procedure, Emergency medical services, Health facilities, Health professions, Infants and children, Hospitals, Maternal and child health, Medicare.

45 CFR Part 84

Administrative practice and procedure, Civil rights, Discrimination, Emergency medical services, Equal access to justice, Federal financial assistance, Government employees, Grant programs, Grant programs – health, Grant programs – social programs, Health, Health care, Health care access, Health facilities, Health insurance, Health professions, Health programs and activities, Hospitals, Individuals with disabilities, Infants and children, Maternal and child health, Medicaid, Medical assistance program, Medical care, Medical and dental schools, Medical facilities, Medical personnel, Medicare, Nondiscrimination, Public health, Public assistance programs, State and local governments.

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 42 CFR Parts 482 and 489 and 45 CFR Part 84 as follows:

TITLE 42—Public Health

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

1. Amend the authority citation for part 482 to read as follows:

Authority: 1 U.S.C. 8; 42 U.S.C. 1302, 1395hh, and 1395rr; 42 U.S.C. 6101;

unless otherwise noted.

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2. Amend section 482.13 by revising paragraphs (a)(1), (b)(1), and (b)(2), and adding paragraph (b)(5) to read as follows:

§ 482.13. Condition of participation: Patient’s rights.

* * * * *

(a) Standard: Notice of rights.

(1) A hospital must inform each patient, or when appropriate, the patient’s representative (as allowed under State law), of the patient’s rights, in advance of furnishing or discontinuing patient care whenever possible. This includes informing the representative of a patient (including an infant born alive at any stage of development, consistent with 1 U.S.C. 8) if and when a “do not resuscitate order” is entered for the patient when the order was not requested by the patient or the patient’s legal representative.

(2) * * *

(b) Standard: Exercise of rights.

(1) The patient has the right to participate in the development and implementation of his or her plan of care. This includes the right for a representative of a patient (including an infant born alive at any stage of development, consistent with 1 U.S.C. 8) if and when a “do not resuscitate order” is entered for the patient when the order was not requested by the patient or the patient’s legal representative.

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(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate. Conditions or symptoms constituting or regarded as disabilities, including prematurity, may only be considered as factors in deeming a treatment or service futile, unnecessary, or inappropriate for a patient (including an infant born alive at any stage of development, consistent with 1 U.S.C. 8) if the hospital makes an individualized assessment of the relevance of such conditions or symptoms to the treatment or service in question and considers the availability of auxiliary aids and services and reasonable modifications for alleviating or mitigating such conditions or symptoms. Hospitals shall not deem a treatment futile, unnecessary, or inappropriate based on stereotypes or bias based on disability, including prematurity, or on an assessment of the relative worth of the life of a patient with a disability (including an infant born alive at any stage of development, consistent with 1 U.S.C. 8).

(3) * * *

(4) * * *

(5) The protections and rights in paragraphs (a)(1), (b)(1) and (b)(2) in this section include a prohibition on steering, encouraging, pressuring, or unduly influencing a patient

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or his or her legal representative, including a parent or guardian of an infant, (including an infant born alive at any stage of development, consistent with 1 U.S.C. 8), on the basis of disability to:

- (i) decline or withhold consent for the provision of life-saving or life-sustaining care;
- (ii) consent to the withdrawal of life-saving or life-sustaining care; or
- (iii) consent to the provision or receipt of any item or service furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing.

TITLE 42—Public Health

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

3. Amend the authority citation for Part 489 to read as follows:

Authority: 1 U.S.C. 8; Secs. 1102 1819, 1820(E), 1861, 1864(M), 1866, 1869, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395i-3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395hh).

4. Add, in paragraph (b), between “Hospital with an emergency department” and “Inpatient,” the following:

Individual includes infants born alive at any stage of development, consistent with 1 U.S.C. 8.

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TITLE 45—Public Welfare

PART 84—NONDISCRIMINATION ON THE BASIS OF HANDICAP IN PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE

5. Amend the authority citation for Part 84 to insert “1 U.S.C. 8;” immediately after “Authority:”

6. Remove § 84.55(b) through (e), and their accompanying notes.

7. Redesignate § 84.55(a) as § 84.55(e).

8. Add new § 84.55(a), (b), (c), and (d) and revise its heading as follows:

§ 84.55. Procedures relating to life-saving or life-sustaining care and healthcare for infants with disabilities.

(a) The provisions of this part apply to the treatment or service of infants with disabilities (or, as used elsewhere in this part, “handicapped infants”), including infants born alive at any stage of development, consistent with 1 U.S.C. 8, to the same extent the provisions would apply with respect to any other individual with, having a record of, or regarded as having, a disability, and, in the case of treatment of a newborn infant, where the newborn infant’s parent or legal representative with legal authority consents to the treatment or service.

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(b) The protections against discrimination in this part prohibit decisions to provide or withdraw life-saving or life-sustaining care made on the basis of:

(1) evaluations of the relative worth of the life of an individual with a disability or disabilities compared to a person without the disability or disabilities.

(2) a belief or assessment that an individual does, or would, impose a burden on caregivers or society based on disability; or

(3) stereotypes or bias based on disability, whether assessed based on the individual's disability status prior to receiving life-saving or life-sustaining care or anticipated disability status after receiving life-saving or life-sustaining care.

(c) Conditions or symptoms constituting or regarded as disabilities, including prematurity, may only be considered as factors in deeming a life-saving or life-sustaining treatment or service futile, unnecessary, or inappropriate for an individual (including an infant born alive at any stage of development, consistent with 1 U.S.C. 8) if the provider makes an individualized assessment of the relevance of such conditions or symptoms to the individual's short-term survivability and considers the availability of auxiliary aids and services and reasonable modifications for alleviating or mitigating such conditions or symptoms. Providers shall not deem such treatment futile, unnecessary, or inappropriate on the basis of any discriminatory factor listed in paragraph (b).

(d) With respect to entities or individuals subject to this part, the protections in paragraph (b) include a prohibition on steering, encouraging, pressuring, or unduly

