

December 4, 2020

via Online Portal (www.regulations.gov)

The Honorable Alex Azar, Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

RE: HHS–OS–2020–0012; Securing Updated and Necessary Statutory Evaluations Timely (RIN 0991–AC24)

Dear Secretary Azar:

The Disability Rights Education and Defense Fund (“DREDF”) appreciates the opportunity to provide comment on HHS’ proposed rule “Securing Updated and Necessary Statutory Evaluations Timely” (hereinafter referred to as the “Regulations Rule”). DREDF is a national cross-disability law and policy center that protects and advances the civil and human rights of people with disabilities through legal advocacy, training, education, and development of legislation and public policy. We are committed to increasing accessible and equally effective healthcare for people with disabilities and eliminating persistent health disparities that affect the length and quality of their lives.

DREDF is gravely concerned with HHS’ proposed Regulations Rule. The proposal would retroactively impose an expiration provision on most HHS regulations and establish “assessment” and “review” procedures to determine which, if any, regulations should be retained or revised. The Regulations Rule is an ill-conceived proposal that would create a tremendous administrative burden for HHS and create chaos across a broad swath of HHS programs and regulated entities, including Medicaid, Medicare, the Food and Drug Administration (“FDA”), and the Centers for Disease Control and Prevention (“CDC”). Additionally, the effects of this increased burden, and the pre-existing regulatory provisions that may be arbitrarily rescinded because of it, will have a particularly devastating effect on low-income people with disabilities who need essential health care services and supports provided under public programs, and rely on substantive and procedural protections detailed in longstanding regulations. Finally, we object to HHS’ truncated 30-day comment period, which is insufficient for a rule with this broad of scope and potentially harmful effects. We urge HHS to immediately withdraw the Proposed Rule.

To: Secretary Azar

RE: DREDF Comment on HHS' Proposed "Regulations Rule" (HHS-OCR-2019-0007)

December 4, 2020

Page 2 of 8

I. The Proposed Rule Is Unnecessary and Would Create An Overwhelming Administrative Burden for HHS

In the Regulations Rule, HHS proposes to set an automatic expiration date for regulations issued by the agency, unless the regulation is subject to an exception¹ or a detailed staff assessment determines that it would *not* have a "significant economic impact on a substantial number of small entities."² If not exempted, then HHS would be required to undertake a comprehensive review, analyzing the continued need for the regulation, any complaints about the regulation, the complexity of the regulation, any duplicative or conflicting regulations, and whether circumstances favor amending or rescinding the rule.³ If HHS does not engage in this comprehensive retrospective review and produce a determination in favor of retaining the regulation, then it would automatically expire ten years after its final issuance date, or two years from the Regulation Rule's effective date, for rules issued more than ten years prior to that date.

HHS asserts that this proposal is necessary in order to ensure that regulatory provisions are regularly evaluated and timely updated. However, there are already numerous mechanisms in place to ensure that HHS regulations are updated when needed—mechanisms that strike the proper balance between timeliness and administrative burden.

For example, HHS annually reviews and updates the Notice of Benefits and Payment Parameters ("NBPP") for health insurance marketplaces, health insurance issuers, and funding methodologies in order to incorporate new information and data. HHS also annually reviews and updates certain Medicare regulations to reflect policy and technical changes and new program parameters. Additionally, it regularly reviews—and revises, when necessary—Medicaid regulations. For instance, in 2002 the Centers for Medicare and Medicaid Services ("CMS")

¹ Exceptions include "Regulations whose expiration pursuant to this section would violate any other Federal law" and "Regulations that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency." HHS, *Securing Updated and Necessary Statutory Evaluations Timely; Notice of Proposed Rulemaking* (RIN 0991-AC24), 85 Fed. Reg. 70096, 70121 (Nov. 4, 2020), available at <https://www.govinfo.gov/content/pkg/FR-2020-11-04/pdf/2020-23888.pdf>. This comment assumes that critical civil rights regulations such as those enacted under Section 504 of the Rehabilitation Act of 1973 and Section 1557 of the Affordable Care Act would be subject to an exception.

² *Id.* at 70119.

³ *Id.* at 70119–20.

To: Secretary Azar

RE: DREDF Comment on HHS' Proposed "Regulations Rule" (HHS-OCR-2019-0007)

December 4, 2020

Page 3 of 8

promulgated regulations implementing statutory changes to improve Medicaid managed care.⁴ Then, in 2015, recognizing the need to update and modernize these regulations, CMS proposed amendments to the Rule.⁵ After considering hundreds of public comments, it published the revised Rule in May 2016.⁶ This Administration, in its own words, then undertook an additional review in 2020 in order to "relieve regulatory burdens; support state flexibility and local leadership; and promote transparency, flexibility, and innovation in the delivery of care."⁷ HHS' contention that it needs to "incentivize" regulation review by imposing a mandatory rescission is simply not supported by the facts or a record of complaints or hardships imposed upon those receiving benefit from, or protection under, an HHS rule that should be rescinded because of insufficiently review.⁸

Further, not only is this Regulations Rule unnecessary, but it will create a massive administrative burden for HHS and its sub-agencies, diverting time and resources away from critical work, including efforts to address the COVID-19 pandemic. HHS asserts that its proposal will promote "administrative simplification."⁹ In fact, HHS itself estimates that the proposal would cost nearly 26 million dollars over 10 years, needing 90 full-time staff positions to undertake the required reviews.¹⁰ Within the first two years, HHS estimates the need to assess at least 12,400

⁴ CMS, *Medicaid Program; Medicaid Managed Care: New Provisions* (RIN 0938–AK96), 67 Fed. Reg. 40989 (June 14, 2002), available at <https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/downloads/cms2104f.pdf>.

⁵ CMS, *Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; Proposed Rules* (RIN 0938–AS25), 80 Fed. Reg. 31098 (June 1, 2015), available at <https://www.federalregister.gov/documents/2015/06/01/2015-12965/medicaid-and-childrens-health-insurance-program-chip-programs-medicaid-managed-care-chip-delivered>.

⁶ CMS, *Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; Final Rule* (RIN 0938–AS25), 80 Fed. Reg. 27498 (May 6, 2016), available at <https://www.govinfo.gov/content/pkg/FR-2016-05-06/pdf/2016-09581.pdf>.

⁷ CMS, *Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care; Final Rule* (RIN 0938–AT40), 85 Fed. Reg. 72754 (Nov. 13, 2020), available at <https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/downloads/cms2104f.pdf>.

⁸ 85 Fed. Reg. at 70099, 70106.

⁹ 85 Fed. Reg. at 70104.

¹⁰ 85 Fed. Reg. at 70116.

To: Secretary Azar

RE: DREDF Comment on HHS' Proposed "Regulations Rule" (HHS-OCR-2019-0007)

December 4, 2020

Page 4 of 8

regulations that are over 10 years old.¹¹ These estimates are conservative, and likely underestimate the time and money involved in the review process and fail to accurately account for complications that may arise. To add to this complexity, the Regulations Rule proposes to define a "regulation" as a provision in the Code of Federal Regulations—that is, it will consider regulations in their codification sequence, rather than in the context of the Final Rule that created them.¹² This is illogical and will serve to further complicate the agency's unwarranted reviews.

This unnecessary administrative burden will adversely affect HHS's ability to focus on the administration of current programs, to issue new regulations, to monitor adherence to existing regulations and guidelines, and to appropriately review current regulations that actually do need modification. To be clear, DREDF does not oppose the idea of modernizing regulations through a targeted regulatory review process. In fact, we have supported the rescission or revision of several regulations that we believe are outdated, burdensome, or otherwise stand in the way of effectuating the rights of people with disabilities. For example, we have advocated for the removal of the outdated and inappropriate Medicare "home use" requirement for coverage of durable medical equipment ("DME"), which significantly limits the mobility devices available to beneficiaries with disabilities. Additionally, the regulations defining skilled therapy services must be updated to reflect the national settlement in *Jimmo v. Sebelius*,¹³ which established that Medicare must cover skilled services not only intended to "improve function", but also to "maintain or prevent deterioration in function."

However, the proposal at hand does not appropriately distinguish between regulations that are legitimately out of date and due for reconsideration and those that provide structure to the existing health care system and are critical to the consumer protections that have been thoughtfully developed over decades. Placing an all-encompassing, burdensome review process solely in the hands of agency staff, on an unreasonably short timeframe, raises the potential for serious upheaval of critical beneficiary-centered regulations simply due to staff time and resource constraints. Especially during crisis situations like the COVID-19 pandemic, it is critically important that HHS have the flexibility and bandwidth to shift focus and respond quickly to immediate needs without the automatic lapse of crucial regulations. The proposed rule would hinder HHS' capacity and effectiveness to carry out COVID-19 and other emergency mandates.

¹¹ 85 Fed. Reg. at 70112. To be specific, HHS states that "because the Department estimates that roughly five regulations on average are part of the same rulemaking, the number of Assessments to perform in the first two years is estimated to be roughly 2,480." *Id.*

¹² *Id.* at 70119.

¹³ No. 5:11-CV-17-CR (D. Vt. Jan. 24, 2013), available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Jimmo-Settlement-Agreement.pdf>.

To: Secretary Azar

RE: DREDF Comment on HHS' Proposed "Regulations Rule" (HHS-OCR-2019-0007)

December 4, 2020

Page 5 of 8

II. The Proposed Rule Would Wreak Havoc Across HHS Programs and Place Integral Regulations in Danger of Arbitrary Elimination

HHS regulations play a critical role in the implementation of HHS policies and programs, including essential public healthcare programs such as Medicare, Medicaid, and the Children's Health Insurance Program ("CHIP"). A strong regulatory framework provides States the clarity they need to run these programs on a day-to-day basis, gives health care providers and managed care plans guidance over time as to their obligations, and explains to beneficiaries their benefits and rights under the law. The Regulations Rule would create legal uncertainty regarding the validity and enforceability of a broad swath of regulations.

Of greater concern, however, is the danger that regulations will be arbitrarily rescinded because there is simply not enough HHS staff or resources to undertake the sweeping review process mandated by the Proposed Rule. Regulatory provisions that do not make it through the complicated and time-consuming review process would summarily expire, potentially leaving vast, gaping holes in the regulatory framework implementing HHS programs and policies.

For example, the Regulations Rule could function to eliminate the Medicaid Managed Care Rule¹⁴ and related Medicaid Access Rule,¹⁵ which require State Medicaid agencies to ensure, respectively, that their managed care provider networks are adequate to meet the needs of their enrolled beneficiaries and that fee-for-service providers are reimbursed at a high enough levels to ensure that adequate care is available in all geographic areas. These rules also contain provisions related to the accessibility of healthcare delivery mechanisms, such as requiring large print taglines on essential documents, providing accessible notices of provider termination from a network, and provider cultural competency training. These provisions are essential to ensuring that all beneficiaries, including beneficiaries with disabilities, have access to the healthcare services and supports that they need. Of particular relevance and importance to disabled

¹⁴ CMS, *Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability; Final Rule* (RIN 0938-AS25), 81 Fed. Reg. 27498 (May 6, 2016), available at <https://www.govinfo.gov/content/pkg/FR-2016-05-06/pdf/2016-09581.pdf>; CMS, *Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care; Final Rule* (RIN 0938-AT40), 85 Fed. Reg. 72754 (Nov. 13, 2020), available at <https://www.govinfo.gov/content/pkg/FR-2020-11-13/pdf/2020-24758.pdf>.

¹⁵ CMS, *Medicaid Program; Methods for Assuring Access to Covered Medicaid Services; Final Rule* (RIN: 0938-AQ54), 80 Fed. Reg. 67576 (Nov. 2, 2012), available at <https://www.govinfo.gov/content/pkg/FR-2015-11-02/pdf/2015-27697.pdf>.

To: Secretary Azar

RE: DREDF Comment on HHS' Proposed "Regulations Rule" (HHS-OCR-2019-0007)

December 4, 2020

Page 6 of 8

beneficiaries is the availability of long-term support and services ("LTSS") providers, particularly in rural areas. The Medicaid Managed Care and Access Rules operate to improve access to the LTSS services on which many people with disabilities rely to live full, integrated lives in their communities. HHS' Proposed Rule places these regulatory provisions at risk of arbitrary elimination—a prospect that would severely impact the rights of disabled Medicaid beneficiaries.

Additionally, the Regulations Rule could place at risk the Home and Community Based Services ("HCBS") Settings Rule.¹⁶ The HCBS Settings Rule was put in place because of concerns that many States and providers were using federal Medicaid dollars dedicated to community-based supports to pay for health care services that were still institutional in nature. Too many so-called "community" options receiving HCBS funds were exercising the same control and isolation over individuals as larger institutions. By articulating a set of minimum requirements for HCBS funding, the Settings Rule ensured that federal funds were used for their intended purpose and that individuals with disabilities had an opportunity to enjoy the autonomy and freedom associated with community life. The Rule requires that entities receiving HCBS funding have a setting that is integrated in the greater community; supports the individual's full access to community life, employment, and control over their personal resources; is selected by the individual from among different options, including those that are non-disability specific and private; optimizes independence in daily activities and associations; and facilitates individual choice in supports and service providers. These requirements were designed to ensure that people with disabilities have the same kind of choice and control over their lives as those not receiving HCBS funding. The Settings Rule was carefully and extensively considered by HHS, after an extensive notice-and-comment period. The proposed Regulations Rule would place its meticulously drafted provisions—and the rights of the disabled beneficiaries they support—at arbitrary risk of periodic elimination. This is simply unacceptable. People with disabilities have fought institutionalization and sought community integration for literally decades, using tools that include direct action, litigation, and advocating for legislative and regulatory changes. Historic injustices are not magically fixed in ten-year periods.

While these are just two examples of the kinds of regulatory provisions that could be thoughtlessly rescinded via the Proposed Rule, there are countless others that affect people with disabilities of all ages. Should this proposal be finalized, approximately 18,000 HHS regulations will be scheduled to automatically expire. The implications of this decision are too broad to

¹⁶ CMS, *Medicaid Program; State Plan Home and Community-Based Services, 5- Year Period for Waivers, Provider Payment Reassignment, and Home and Community-Based Setting Requirements for Community First Choice and Home and Community- Based Services (HCBS) Waivers; Final Rule* (RIN 0938-AO53), 79 Fed. Reg. 2948 (Jan. 16, 2014).

To: Secretary Azar

RE: DREDF Comment on HHS' Proposed "Regulations Rule" (HHS-OCR-2019-0007)

December 4, 2020

Page 7 of 8

fathom, and certainly too broad to analyze in the exceedingly short comment period that HHS has provided to the public.

III. HHS Does Not Have the Legal Authority to Impose Automatic Expiration Dates on Regulatory Provisions

The Proposed Rule attempts to justify its automatic expiration dates through citation to the Regulatory Flexibility Act ("RFA"), a federal law that requires each agency to publish "a plan for the periodic review of the rules issued by the agency which have or will have a significant economic impact upon a substantial number of small entities."¹⁷ HHS, however, misinterprets the meaning of this forty-year old law. By its own terms, the RFA was intended to require "periodic review" of certain rules; nothing in its terms authorizes a blanket, retroactive expiration of duly promulgated regulations.

In fact, the Proposed Rule directly contradicts the Administrative Procedure Act ("APA"), another federal law that specifically establishes the mandatory procedures for agency rulemaking. With the APA, Congress established clear standards that agencies must follow when seeking to promulgate, rescind, or modify regulatory provisions. The APA requires public notice-and-comment rulemaking in all of these scenarios.¹⁸

HHS argues that, through this Proposed Rule (which has been posted for public comment), it is following the APA's notice-and-comment requirements and amending all previously promulgated regulations to impose end dates.¹⁹ Even setting aside the fact that the comment period was truncated to only 30 days, HHS' argument is deeply flawed. We do not dispute that federal agencies can amend existing regulations. However, the Regulations Rule would modify thousands of separate, distinct rules across HHS and its various sub-agencies in a single stroke.

¹⁷ 5 U.S.C. § 610(a) (In the case of the RFA, periodically is defined as 10 years, unless such review is not feasible, in which case the review can be extended another 5 years).

¹⁸ 5 U.S.C. § 551(5); see also Maeve P. Carey, Specialist in Government Organization and Management, *Can a New Administration Undo a Previous Administration's Regulations?*, Congressional Research Service (Nov. 21, 2016), <https://fas.org/sgp/crs/misc/IN10611.pdf> ("In short, once a rule has been finalized, a new administration would be required to undergo the rulemaking process to change or repeal all or part of the rule."); Office of Information and Regulatory Affairs, Office of Management and Budget, *The Reg Map 5* (2020) (noting that "agencies seeking to modify or repeal a rule" must follow the same rulemaking process they would under the APA).

¹⁹ 85 Fed. Reg. at 70104, n.85, 86 (citing to separate, specific rulemakings modifying interim final rules implementing mental health parity and foreign quarantine provisions, respectively).

To: Secretary Azar

RE: DREDF Comment on HHS' Proposed "Regulations Rule" (HHS-OCR-2019-0007)

December 4, 2020

Page 8 of 8

The APA requires that regulatory review take place on an individual basis, with specific fact-finding relevant to the individual rule at issue. It is simply impossible to properly review 18,000 regulations in one blanket amendment. Interested stakeholders and members of the public cannot be expected to anticipate and comment on the thousands of regulations that will quickly come up for review over the next decade, particularly when those individual regulations will not even be individually noticed for comment because the Regulations Rule has automatically amended them years ago. This Proposal will not withstand scrutiny under the APA.

IV. Conclusion

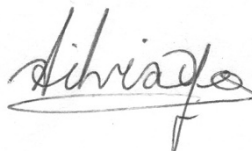
The proposed Regulations Rule is a thinly-veiled attempt to sabotage and destroy duly promulgated regulations by retroactively imposing an arbitrary end date on nearly all existing HHS regulations. This rule is unnecessary, will wreak havoc on current HHS programs, and will tie the hands of the incoming Administration and detract from critical issues like the COVID-19 pandemic by tying up Agency resources in ongoing time-consuming review procedures. We strongly oppose this Rule and urge HHS to withdraw it immediately.

Thank you again for the opportunity to comment on the Proposed Rule. Please do not hesitate to contact us if you have any questions about the above.

Sincerely,



Carly A. Myers
Staff Attorney



Silvia Yee
Senior Staff Attorney