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U.S. Department of Health and Human Services
Office for Civil Rights
Attention: 1557 NPRM
RIN 0945-AA02
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, SW
Washington, D.C. 20201

RE: Nondiscrimination in Health Programs and Activities, Notice of Proposed Rulemaking

To Whom It May Concern:

The U.S. Chamber of Commerce (the "Chamber") submits these comments in response to the Notice of Proposed Rulemaking ("NPRM") regarding Section 1557 of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 ("ACA").[1] This NPRM was published in the Federal Register on September 8, 2015 by the Department of Health and Human Service's ("HHS's" or "Department's") Office of Civil Rights ("OCR").[2] Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age or disability in certain health programs and activities. Section 1557 of the ACA provides that "an individual shall not, on the grounds prohibited under title VI, of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, or Section 504 of the Rehabilitation Act of 1973, be excluded from participation in, be denied benefits of, or be subjected to discrimination under any health program or activity, any part of which is receiving Federal financial assistance, or under any programs or activity that is administered by an Executive Agency or any entity established under this title [Title I of the ACA] (or amendments)."[3]

The Chamber is the world's largest business federation, representing the interests of more than three million businesses and organizations of every size, sector and region, with substantial membership in all 50 states. More than 96 percent of the Chamber's members are small

[1] The Patient Protection and Affordable Care Act, Pub. L. No. 111-148, amended by Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152 (2010). [hereinafter referred to as "ACA"].
[2] Notice of Proposed Rulemaking, 80 Fed. Reg. 54,172-54,221. (September 8, 2015) (to be codified at 45 C.F.R. pt. 92) [hereinafter referred to as the "NPRM"] http://www.gpo.gov/fdsys/pkg/FR-2015-09-08/pdf/2015-22043.pdf
[3] §1557 (a) of the ACA and NPRM at 54,172.

businesses with 100 or fewer employees, 70 percent of which have 10 or fewer employees. Yet, virtually all of the nation's largest companies are also active members. Therefore, the Chamber is particularly cognizant of the problems of smaller businesses, as well as issues facing the business community at large. Each major classification of American business – manufacturing, retailing, services, construction, wholesaling, and finance – is represented. These comments have been developed with the input of member companies with an interest in improving the health care system.

OVERVIEW

The Chamber strongly supports the protection of individuals against discrimination on the basis of race, color, national origin, sex, age, or disability. Nevertheless, we are very concerned about an effort to impose a new regulatory regime on all programs of an entire entity based solely on the fact that one program administered by that entity receives federal dollars.[4] This issue is being analyzed in great detail by other commenters[5] and we will, therefore, focus on the defects of the proposal's economic analysis as discussed in detail below.

Inadequate Regulatory Impact Analysis

Executive Orders 12866 and 13563 require agencies to consider the costs and benefits of alternative approaches to every proposed regulation, including the approaches of no regulation and of an informative rather than prescriptive approach, and to select the alternative likely to yield the greatest net benefit to society. Where benefits cannot be reliably measured in monetary terms, agencies must select the least costly approach among those providing similar benefits. Conducting a thorough and accurate regulatory economic impact analysis to inform the decision to regulate and the selection of a specific regulatory approach is an agency's best defense against the charge of arbitrary and capricious rulemaking. Failure to present an adequate analysis suggests that the agency may have ignored more effective or efficient alternatives and imposed unnecessary burdens on citizens.

For regulations that are economically significant (having a cost impact in any one year in excess of $100 million), the agency is also required to submit their economic analysis to the Office of Information and Regulatory Affairs (OIRA) for review. This NPRM was found to be economically significant and the Department's analysis was submitted to OIRA for review. The fact that the errors and omissions detailed below apparently escaped OIRA's attention is cause for additional concern.

[4] This is not a unique issue. For example, both Congress and the Office of Federal Contract Compliance Programs (OFCCP) have acknowledged that there are limitations on the requirements they may impose on private actors who have certain relationships with government programs, including in the area of healthcare. *See* Section 714 of the 2012 National Defense Authorization Act (limiting OFCCP jurisdiction over medical providers that are subcontractors in TRICARE); *see also* OFCCP FAQs, http://www.dol.gov/ofccp/regs/compliance/faqs/offaqs.htm (noting that "hospital or other health care provider is not covered under the laws enforced by OFCCP if its only relationship with the Federal government is as a participating provider under Medicare Parts A and B and Medicaid.").

[5] Letter submitted to the docket by ERISA Industry Committee (ERIC) November 9, 2015.

The regulatory economic impact analysis presented by the Department for this NPRM omits two salient compliance cost elements, which are detailed below. For those cost elements that the Department *does* identify, the cost calculations contain notable errors or unsupported assumptions that tend to underestimate the likely cost; and these are also detailed below. The Department failed to present an adequate analysis of regulatory alternatives. Alternatives should be examined in as thorough detail as the approach selected for proposal, but the Department's discussion of alternatives is cursory and lacks cost specificity. The Department has not considered and analyzed the alternatives of no regulation, nor the alternative of an informative approach rather than the proposed prescriptive approach, both of which are required to be considered by Executive Order 12866.[6] While the previously issued Request for Information was an initial step, the Department could go further to inform and encourage insurance and service providers to be mindful of the issue and to voluntarily adopt necessary protections before proceeding to a highly prescriptive regulation,. The Department could draw up an example of a model policy which would suggest appropriate action on the part of the covered entities.

In its NPRM the Department has also failed to adequately analyze and consider the benefits of the proposed rule and failed to examine how different benefits may vary in relation to specific compliance cost factors. For example, how effective is the extent and intensity of employee training for reducing the incidence of discrimination? Are there potential unintended consequences of the NPRM that may generate offsetting "dis-benefits?" This question is examined in detail below.

The Department estimates that the NPRM will impose aggregate costs of $939.4 million over the first five years, much of which will be concentrated in the first year of implementation.[7] Consideration of the notable omissions, errors, and questionable assumptions found in the Department's analysis suggests that the actual cost may be several times higher. Costs of this magnitude are a burden that may sensibly affect the cost and availability of health insurance and of health care services, adversely impacting achievement of the Affordable Care Act's goals of expanding access to health insurance and of improving the health of citizens. The Department has not adequately considered these indirect, derivative impacts of the NPRM.

The inadequacies of the Department's regulatory impact analysis are serious and point to one conclusion: The Department's present proposal is premature. The Department should withdraw its proposal and conduct research and collect data to support a more thorough analysis of costs and benefits. This criticism should neither be interpreted to imply that some form of nondiscrimination regulation is unwarranted, nor should this criticism be interpreted to imply that the benefits of protection against discrimination are not real. This criticism is directed at the inadequacy of the Department's process of analysis to design an effective and efficient regulation approach. The Department's failure to adequately analyze and design its NPRM will

[6] Executive Order 12688, Section 1(a) states "In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alterative of not regulating." Section 1(b)(3) states "Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or market permits, or providing information upon which choices can be made by the public."

[7] NPRM, at 54,208.

ultimately be seen as a disservice to the victims of discrimination whom the Department is charged to protect because in its rush to publish some regulation, the Department has not allocated resources properly to ensure that they have published the right regulation. The result may be delayed relief for victims of discrimination (whether intentional or unintentional). The following sections examine in detail the inadequacies of the Department's analysis summarized above.

Omitted Regulatory Compliance Familiarization Costs

Before entities can comply with a regulation, entities must learn and understand what the regulation requires. The regulatory familiarization process includes both careful reading of the final regulation by each potentially affected person and an assessment of whether and how the rule affects his or her activities, responsibilities, liabilities and rights. Even entities who are not subject to the rule (e.g., insurers or health care service providers who receive no Federal funding) will need to expend some time and resources with regulatory familiarization to establish that conclusion. For those that do have responsibilities and liabilities under the rule, the familiarization process will include further effort to assess what gaps in current policies and practices may exist and what steps need to be taken to address them. This does not include the effort actually necessary to complete the compliance actions, but only the assessment of which issues need to be addressed.

For small entities, such as a single physician office, the familiarization process may be fairly simple and require only a few hours of effort by the proprietor. But for larger entities the initial familiarization process may entail collaboration and consultation among many executive officers as well as consultation with outside legal counsel. The NPRM will impose on affected entities serious legal liabilities and exposure. Corporate officers will need to exercise due diligence to understand and to manage these new or expanded liabilities. A corporation faces both the risk of significant economic damage awards if found liable for discrimination (even if the discrimination was unintentional), and the risk of stockholder lawsuits against officers and directors if discrimination liability awards are found to be the result of negligent management compliance with the rule. These serious potential liabilities suggest the need for significant investment in the familiarization process. The Department should conduct retrospective evaluation of compliance with previous regulations to establish a credible basis for estimating the familiarization costs that this NPRM will impose. As part of its regulatory impact analysis and regulatory decision process, the Department should also consider alternative approaches (such as plain regulatory language and compliance assistance information) that may simplify the initial familiarization process for the affected public.

The Department has identified 278,565 health care service and insurance entities potentially affected by the proposed rule.[8] An optimistic average estimate of 8 hours per entity for executive attention to regulatory familiarization at a full opportunity cost (including properly computed overhead) of $180 per hour[9], yields a familiarization cost of $400 million, nearly half

[8] NPRM, at 54200, Table 3.

[9] This is a lower bound estimate of the time and full opportunity cost parameters. For some entities the time requirement and opportunity cost of labor time and the resulting familiarization cost may be much greater

of the $900 million of compliance costs that the Department has recognized. Since 278,565 is the number of entities that the Department estimates will be affected, the actual initial familiarization cost will likely be higher when the number of unaffected entities that nevertheless must expend some familiarization effort to determine their non-covered status is added. The total familiarization cost may also be increased by consideration of the significantly higher familiarization effort required for larger than average entities.

Omitted Litigation Cost Impact

The NPRM discusses several private rights of action for certain claims of discrimination.[10] The Department has not analyzed and considered how these rights may impact the incidence and costs of litigation that may arise. The Department should consider the litigation cost impacts of both valid complaints and of complaints that turn out to be unfounded. The Department should also consider the behavioral impact of exposure to private right of action liability on the covered entities: What additional costs will covered entities incur to mitigate the litigation risk and how will the availability of health services and insurance to the public be affected by the likely response of affected entities to this risk? Also, the Department should undertake research based on related private right of action statutes and rules to assess credibly the likely cost impact in relation to economic benefits and transfers arising from exercise of private rights of action. In circumstances where an agency does not have discretion or authority to modify a requirement, it remains important for the agency to report fully the likely cost of the requirement so that Congress and the public can be properly informed of all costs associated with the regulation.

Erroneous Calculation of Overhead Costs

Throughout the Department's analysis of compliance cost there are calculations of labor time effort multiplied by a unit labor cost factor. The Department attempts to adjust estimated direct labor wage amounts to add an amount for non-wage employee compensation (benefits such as insurance, retirement savings contributions, and paid leave) and for indirect overhead (office space, equipment, administrative services, information technology support, supervision, etc.). The Department uniformly adds 100% of the wage amount as an estimate of the benefits and overhead amount. Data from the Bureau of Labor Statistics establishes that non-wage benefits average a 30% (or more) addition to direct wages. This leaves the Department's allowance for overhead as 70% of direct wages, which proportion is not supported by any empirical evidence that the Department presents. Examination of overhead rates that Federal agencies pay to contractors for labor services under General Services Administration government-wide contract vehicles shows that wage markups for benefits and overhead are typically 200% or more. This suggests that the Department's estimates of labor costs throughout the analysis for this NPRM are under-estimated by a one-third factor. The Department's published labor-driven cost elements should be increased by a factor of 1.33 to present a more reasonably correct result.[11]

[10] NPRM, P. 54192.

[11] This is a conservative adjustment. Some data suggest that a factor of three times direct wages to fully account for overhead costs may be justified.

For example, the estimated cost of complaint investigations, published by the Department as $504.3 million over five years[12] would be more accurately estimated as at least $670.7 million for the same time period to account for overhead costs fully. It should be noted that this figure may be subject to further upward revision to account for other factors of error or omission.

Unfounded Assumptions Regarding Compliance Staff Level

In a number of compliance cost calculations the Department assumes that the compliance work will be carried out by an administrative (clerical) employee or by a mid-level manager. It does not appear that these determinations of staff responsibility level are based on any empirical analysis of actual staffing assignments made by regulated entities in compliance with similar regulations. Considering the potential liability of the company in the event that the compliance activity is not carried out correctly, it seems that assignment of some or all of such tasks to senior executives or legal counsel would be most likely. The Department needs to conduct further research, including field interviews with affected companies to provide an empirical basis for its assumptions regarding the selection of staff to conduct compliance activities as well as the amounts of time to be allocated. The ultimate compliance costs of a proposed regulation are highly sensitive to these parameters. At the very least, the Department should present cost estimates that provide a range based on alternative parameter values.

Unfounded Assumption Regarding Training Incidence

The Department's analysis assumes that only half of employees in affected entities will receive training. The Department provides no empirical evidence to support the credibility of this assumption. It appears to have been adopted as an expedient to reduce the compliance cost estimate. The Department could have tested the assumption by conducting surveys of workers in potentially affected workplaces to determine their knowledge and attitudes related to the nondiscrimination objectives of the NPRM; but the Department did not do this.

Even though the Department has not included an explicit training component in the NPRM text, the Department's analysis makes it clear that training is an expected behavioral outcome of the NPRM, and one that the Department intended. Given the private right of action provided through the NPRM and the extensive discussion of training in the Department's proposal, it is reasonable to expect that inadequate training could be cited by private litigants seeking monetary damages from a company arising from perceived discriminatory actions or remarks by an employee.

Given the significant liability risk that the NPRM imposes, it seems more reasonable to assume that a prudent employer would provide training to 100% of employees initially. This more reasonable assumption would double the Department's estimate of $382.8 million for training to $765.6 million. Further adjustment by a factor of 1.33 to account for the Department's under estimation of overhead costs, as described previously, results in an initial training cost estimate for the proposed rule of $1.018 billion. In addition, the Department failed to account for on-

[12] NPRM, at 54,208, Table 5.

going training in future years for new employees (replacement of normal turnover and employment growth) and for retraining of current employees. The continuing need to assess employees' knowledge and compliance and to provide periodic testing and retraining is an important component for effectiveness of the NPRM that the Department has overlooked.

Failure to Establish a Credible Pre-Regulation Compliance Baseline

The Department repeatedly asserts that the real costs of the NPRM may be less than forecast because many employers are already subject under other laws and regulations to the duties and liabilities consolidated in the NPRM. If this is so, the Department should have undertaken surveys of the affected entities prior to proposing this NPRM to accurately measure the extent of prior compliance. This also applies to voluntary activities of employers not strictly required by previous rules or statutes. If there is significant baseline compliance that will not be changed by the NPRM, that is a legitimate basis for reducing the net compliance cost ascribed to the proposed rule, but it is a reduction that must be established by empirical evidence, not speculative conjecture. It is fully within the authority and resources of the Department to conduct research to establish a credible estimate of the pre-rule compliance baseline. The fact that the Department has not done so is further evidence that the Department has prematurely published a NPRM that has not been adequately analyzed and prepared.

Inadequate Analysis of Alternatives

The Department's regulatory impact analysis includes a section in which alternatives considered and rejected are discussed, but the discussion is neither adequate, nor complete. The Department's discussion of these alternatives is not analytical. The discussion presumes facts not supported by empirical evidence. Most importantly, the discussion does not address the alternatives that Executive Order 12866 mandates that it consider: (1) no regulation, and (2) an information-based approach to modify market behavior.

The alternative of "no regulation" should be understood properly. It does not mean an irrevocable decision to not regulate ever; it means a decision to not regulate now. Such a decision may be coupled with a decision to collect data and to monitor the development of conditions in the subject market. Such a decision would be consistent with the trend toward reduced discrimination and discrimination-based losses to women and other subject populations that the Department's own presentation documents.[13] The Department should explicitly consider the question of whether the marketplace and changing social norms are moving with sufficient speed toward a resolution of the perceived problem without the need for overt government intervention by regulations that add to the burdens imposed by the statutory language of ACA Section 1557. Not regulating now would permit the Department to continue to monitor the situation with the prospect of regulating in the future, if voluntary progress is not sufficient. The formal announcement that the government is not presently proceeding with a prescriptive rule,

[13] NPRM, p. 54209: "Since 2013, the uninsured rate for women has declined by 7.7 percentage points, resulting in nearly 7.7 million women gaining health insurance as of 2015. Similarly, uninsured rates for LGBT individuals have dropped 8% since 2013, to approximately 20%."

but may do so at some future time, might be an appropriate incentive for further voluntary progress.

An information-based approach could be an effective complement to the "no-regulation-now-but-we-are-watching" approach. Information such as model policies and publication of data regarding the incidence of problematic conditions could promote the acceleration of voluntary trends already underway. A particular concern may be unintentional discrimination, discriminatory behaviors arising from insensitivity or ignorance. Educational and informational approaches may be much more effective responses to unintentional behavior than prescriptive regulation, which may be counterproductive by motivating defensive reactions.

Inadequate Analysis of Benefits

The Department's assessment of benefits is unnecessarily qualitative and vague. The benefits have not been identified in sufficient detail to enable one to distinguish the benefits of the proposed regulatory approach from alternatives. Even when an agency can legitimately claim that estimating benefits in monetary terms is difficult or impossible, it is usually possible to characterize benefits by some quantitative measure. In this case, for example, it is reasonable to ask how many individuals experience discrimination with respect to each category of discrimination described by the Department. What is the incidence of discrimination associated with each type of covered entity? How do these metrics change when alternative approaches to regulation are examined?

The Department's regulatory analysis presents results of several surveys that document a large proportion (half) of a subject population reporting "some form of discriminatory treatment by providers when receiving medical care,"[14] and that 26.7% were refused needed care. This is a useful starting point for the analysis of regulatory benefits, but it is not sufficient by itself. The report cited is from a 2010 survey and no detail is provided to facilitate evaluation of the statistical robustness of the results. Since 2010 conditions and attitudes affecting the potential for discrimination may have changed significantly, especially with respect to discrimination on the basis or sex, sexual orientation or gender identification. The reports cited in the Department's discussion of the need for and benefits of the NPRM should have motivated the Department to conduct its own surveys to establish the current conditions on a clearly robust statistical basis. In particular, such further research could have better informed the Department's decision to adopt the proposed highly prescriptive regulation rather than the alternative of an information-based approach that Executive Order 12866 directs agencies to consider in the context of every rulemaking decision. The analysis as presented does not reveal whether or not the Department could have obtained an equal or better outcome for the benefit of the subjects of discrimination by a less prescriptive approach.

The Department has not considered whether the proposed approach may have unintended adverse consequences for the victims of discrimination by reducing their overall access to affordable services. Will the proposed prescriptive approach increase risk of private action law suits and liability for service providers who are covered because they receive Federal funds and

[14] NPRM, at 54208.

thereby have the unintended consequence of encouraging some number of providers to withdraw from the covered market (e.g., refuse payments from Federal insurance sources), rather than amend their policies and practices to conform with the requirements of the NPRM? The Department should have conducted sufficient research to answer this question with some degree of certainty.

The Department's benefit analysis does not provide any explanation to justify the proposed approach in preference to a less prescriptive alternative.[15] The Department's discussion of the recent improvements in insurance coverage and access to services for women and other subject populations actually provides an empirical basis for the alternative approach suggested. There may be a risk, which the Department has not considered, that a too heavy-handed regulatory intervention at this time could bring a halt to the significant progress that has recently been made.

CONCLUSION: A PREMATURE AND ILL-CONSIDERED NPRM

The considerations presented above demonstrate that the NPRM as proposed by the Department has not been sufficiently informed by research and analysis. The Department has underestimated the compliance costs of its proposed highly prescriptive and bureaucratic approach. Finally, before a final rule is issued, we urge that the Department provide appropriate economic analysis regarding alternative regulatory approaches and the likely economic impact of the approach they take, in order to fulfill their obligations under the Executive Orders 12866 and 13563. We look forward to continuing to work together in the future.

Sincerely,

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[15] 80 FR 173, p. 54209.