DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 75

Notification of Nonenforcement of Health and Human Services Grants Regulation

AGENCY: Office of the Secretary, HHS.

ACTION: Notification of exercise of enforcement discretion.

SUMMARY: This notification is to inform the public that the U.S. Department of Health and Human Services (HHS) has determined that the rulemaking that resulted in the regulatory provisions promulgated on Dec. 12, 2016, regarding HHS's grant regulations, raises significant concerns about compliance with the Regulatory Flexibility Act. The provisions will not be enforced pending a repromulgation that complies with the Act.

DATES: [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Richard Brundage at (202) 401-6107.

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services has determined that the rulemaking which promulgated or amended 45 CFR 75.101(f), 75.110(a), 75.300(c) and (d), 75.305(a), 75.365, 75.414(c) and (f), and 75.477, published at 81 FR 89393 (Dec. 12, 2016), raises significant concerns about compliance with the requirements of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq*. The Department has accordingly determined to exercise its enforcement discretion not to enforce the regulations until they have been repromulgated with a proper RFA analysis.

I. STATUTORY BACKGROUND

The RFA generally requires that when an agency issues a proposed rule, or a final rule (after publishing a proposed rule) pursuant to section 553(b) of the APA or another law, the agency must prepare a regulatory flexibility analysis that meets the requirements of the RFA and publish such analysis in the Federal Register. 5 U.S.C. 603, 604. The RFA is a "[p]urely procedural" statute, but "set[s] out precise, specific steps an agency must take." *Nat'l Telephone Co-op Ass'n v. FCC*, 563 F.3d 536, 540 (D.C. Cir. 2009) (internal quotation marks omitted). Specifically, the RFA normally requires agencies to describe the impact of a rulemaking on small entities by providing a regulatory impact analysis. Such analysis must address the consideration of regulatory options that would lessen the economic effect of the rule on small entities. The RFA defines a "small entity" as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA)[1]; (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. 5 U.S.C. 601(3)-(6).[2] The requirement does not apply if the head of the agency "certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities." *Id.* section 605(b). The agency must, however, publish the certification in the Federal Register at the time of publication of the proposed or final rule, "along with a statement providing the factual basis for such certification." *Id.* The RFA also requires the agency to provide the certification and the statement with the factual justification to the SBA Chief Counsel for Advocacy. *Id.*

[1] Depending on the industry, SBA considers businesses to be small by virtue of having less than between $7.5 million and $38.5 million in average annual revenue.

[2] The Department considers a rule to have a significant economic impact on a substantial number of small entities if at least 5% of small entities experience an impact of more than 3% of revenue.

If the agency head has not waived the requirements for a regulatory flexibility analysis in accordance with the RFA's waiver provision, and no other RFA exception applies, the agency must prepare the regulatory flexibility analysis and publish it in the Federal Register at the time of promulgation or, if the rule is promulgated in response to an emergency that makes timely compliance impracticable, within 180 days of publication of the final rule. 5 U.S.C. 604(a), 608(b).[3] In addition, the RFA provides for judicial review of an agency's compliance with its provisions under some circumstances, which can result in a court ordering the agency to take corrective action by remanding the rule to the agency and deferring enforcement of the rule against small entities. *Id.* section 611(a)(4).

II. ABSENCE OF RFA ANALYSIS OR CERTIFICATION

The rulemaking that promulgated and amended 45 CFR 75.101(f), 75.110(a), 75.300(c) and (d), 75.305(a), 75.365, 75.414(c) and (f), and 75.477, published at 81 FR 89393 (Dec. 12, 2016), raises significant concerns about compliance with the requirements of the RFA, 5 U.S.C. 601 *et seq.* The Department neither performed the RFA analysis described in 5 U.S.C. 602-604, nor expressly certified that the rules "will not . . . have a significant economic impact on a substantial number of small entities" and provided a statement with the factual basis for such certification as provided for by section 605(b). *See* 81 FR 89393 (Dec. 12, 2016). The rulemaking simply declared that it would "not have a significant economic impact beyond

[3] Section 608(b) provides that except as provided in section 605(b), an agency head may not waive the requirements of section 604 for final rules. An agency head may delay the completion of the requirements of section 604 of the title for a period of not more than one hundred and eighty days after the date of publication in the Federal Register of a final rule by publishing in the Federal Register, not later than such date of publication, a written finding, with reasons therefor, that the final rule is being promulgated in response to an emergency that makes timely compliance with the provisions of section 604 of the title impracticable. If the agency has not prepared a final regulatory analysis pursuant to section 604 of the title within one hundred and eighty days from the date of publication of the final rule, such rule shall lapse and have no effect. Such rule shall not be repromulgated until a final regulatory flexibility analysis has been completed by the agency. 5 U.S.C. 608(b).

HHS's current regulations," without even mentioning small entities or grappling with the obvious interests of such entities that should have been protected by the RFA process. The Department is accordingly exercising its enforcement discretion and as such, these regulatory provisions will not be enforced, pending repromulgation.

The Department failed to make the certification, and provide the factual statement, described by the statute.

Where an agency engaged in notice and comment rulemaking pursuant to section 553 does not perform a RFA analysis, the head of the agency normally must certify that a rule will not have a significant impact on small entities, and the agency must ordinarily provide a statement that lays out the facts that support the certification. The agency's Federal Register publication must, thus, include a certification under section 605(b) that discusses the impact of a rule on a substantial number of small entities *and* "a statement providing the factual basis for such certification." While this is not a high bar, the Government must, at a minimum, show that it made a reasonable, good faith effort to consider at least some facts relevant to small entities impacted by the rule. *Compare North Carolina Fisheries Ass'n, Inc. v. Daley*, 16 F. Supp. 2d 647, 651-53 (E.D. Va. 1997) (finding that certification was noncompliant because it did not discuss any facts regarding the impact on small entities in the time period subject to the rule), *with Nat. Women, Infants and Children Grocers Ass'n v. Food and Nutrition Serv.*, 416 F. Supp. 2d 92, 108-09 (D.D.C. 2006) (holding that certification complied because it explained that the challenged rule applied to the states, which had varying market conditions), *and Cactus Corner, LLC v. U.S. Dep't of Agric.*, 346 F. Supp. 2d 1075 (E.D. Cal. 2004) (finding that certification complied because it defined and discussed the small wholesalers impacted by the rule and made predictions about the likely impact of the rule).

In the preamble to the December 12, 2016 final rules, the Department stated it had an obligation under the RFA to "provide a final regulatory flexibility analysis or to certify that the rule[s] will not have a significant economic impact on a substantial number of small entities." 81 FR at 89394. It then listed a subset of the regulatory changes: aligning the grants regulation at part 75 "with various regulatory and statutory provisions," implementing Supreme Court decisions, and codifying long-standing policies. Without explaining whether or how these regulatory changes might apply to small entities, the Department simply concluded that, "[i]n order to ensure that the public receives the most value, it is essential that HHS grant programs function as effectively and efficiently as possible, and that there is a high level of accountability to prevent waste, fraud, and abuse. The additions provide enhanced direction for the public and will not have a significant economic impact beyond HHS's current regulations." *See* 81 FR at 89394.[4]

This statement in the Federal Register raises serious questions about compliance with the RFA's requirement that the agency head must certify that the rules will not have a significant economic effect on a substantial number of small entities. The statement fails to mention the economic impact on small entities in particular or to even acknowledge that the regulation would apply to small entities. Furthermore, there is nothing in the final rules that provides a factual basis for any inference that the rules would not have a significant economic impact on a substantial number of small entities. Indeed, if anything, there are indications that the rulemaking likely did have a significant economic impact on a substantial number of small

[4] The RFA discussion in the preamble to the proposed rule was virtually identical. *See* Health and Human Services Grants Regulation, 81 FR 45270, 45272 (July 13, 2016).

entities. The absence of a factual basis for a required section 605 certification, too, would be inconsistent with the requirements of the RFA. *See* 5 U.S.C. 605(b).

The rules were not submitted to the SBA Chief Counsel for Advocacy.

When a certification is required, the RFA further requires that the agency "provide such certification and statement to the Chief Counsel for Advocacy of the Small Business Administration." 5 U.S.C. 605(b). The Chief Counsel for Advocacy of the SBA maintains records of the proposed and final rules submitted to it pursuant to the RFA. The Office of the Chief Counsel has informed the Department's General Counsel that it does not have a record of having received the rules pursuant to the RFA.

The rules may have affected a significant number of small entities.

The provisions in the final rules may have affected a significant number of small entities, which underscores why Congress prohibited agency heads from waiving the requirement to conduct an otherwise required regulatory impact analysis except in the narrow circumstance where an agency can provide the factual basis for a certification by the agency head that there is no significant economic impact on a substantial number of small entities.[5] For example, § 75.477(b) precludes a grantee from including as allowable costs those payments that it may make to the Internal Revenue Service in lieu of providing minimum essential coverage (MEC) to its employees. While nearly all large employers offer their employees MEC, in 2015, among companies with 50 to 199 employees, around 8 percent did not. The 8 percent equates to approximately 14,000 small businesses. *See* http://files.kff.org/attachment/report-2015-

[5] Even in the case of an emergency, the agency must conduct a regulatory flexibility analysis. Congress simply gave the agency an additional 180 days to conduct the analysis in case of an emergency, underscoring how important Congress considered the regulatory flexibility analysis to be. *See* 5 U.S.C. 608(b).

employer-health-benefits-survey at 44; https://www.sba.gov/advocacy/firm-size-data (2014). Moreover, if an entity (including governmental or non-profit entities) with at least 50 full-time employees failed to meet the MEC requirements, it could be assessed a penalty equal to the number of its full-time employees for the year (minus up to 30 employees) times $2,000 if at least one full-time employee purchased health coverage with premium tax credits through the health insurance exchange. Any reasonable certification under section 605(b) necessarily would have had to reflect the potential impact on those 14,000 small businesses from this single provision.

A similar showing would have been sensible to perform with respect to the other regulatory provisions contained in the rulemaking that culminated in the December 12, 2016 final rules. Indeed, the data that existed at the time of the rulemaking revealed that various provisions could, in fact, affect a significant number of small entities. For example, § 75.414(c) limits reimbursement for indirect costs on training grants to eight percent. The proposed rule (*see* 81 FR 45270 (July 13, 2016)) indicated that the amendment to paragraph (c) reflected HHS's longstanding policy. However, under the Richardson Waiver (*see* 36 FR 2532 (Feb. 5, 1971)), such policy, absent rulemaking, is not binding. Thus, there was no valid, binding limit on reimbursement of indirect costs prior to the issuance of this rule, and no corresponding showing of the economic implications for small entities, including non-profits, of this new limitation on overhead reimbursement. A proper RFA analysis likely should have considered the effect that moving from a nonbinding policy to binding rule would have on small entities. *Cf. Am. Federation of Labor v. Chertoff*, 552 F. Supp. 2d 999, 1013 (N.D. Cal. 2007) (noting "serious questions [about] whether DHS violated the RFA" when it refused to conduct a final flexibility analysis about a rule that "as good as mandates costly compliance with a new 90-day

timeframe"). There was also no showing concerning § 75.300(c) and (d), which may impose compliance costs on recipients by subjecting the recipients to conflicting statutory and non-statutory requirements.

The regulatory provisions promulgated in the final rules will not be enforced pending rulemaking.

As described above, unless waived pursuant to section 605(b), the RFA generally requires an agency to prepare a final regulatory flexibility analysis. *See* 5 U.S.C. 604(a), 611(a). The preparation of such analysis may be delayed by up to 180 days after the publication of the final rule in cases of emergency. *See* 5 U.S.C. 608(b). Moreover, flawed RFA analyses have been the basis for judicial review of rulemakings.

Because the Department has serious concerns about whether the RFA analysis performed here complied with the RFA, the Department is announcing that it will not enforce the regulatory provisions, pending repromulgation of the Rule. The majority of the Department's grantees are small entities,[6] and the RFA process undertaken with respect to this Rule raises significant concerns about whether their interests were protected in the manner the statute prescribes. Rather than apply a nonenforcement policy only to small entities, however, the Department is exercising its discretion to not enforce the rules with respect to any grantees until the rules have been properly re-promulgated with an impact analysis that hews to the requirements of the RFA. Applying these rules differently to agency grantees depending on size would be unfair, create increased compliance costs for all entities as they seek to determine whether they are or are not

[6] *See, e.g.*, https://taggs.hhs.gov/ReportsGrants/GrantsByRecipClass.

still subject to the rules, and impose additional administrative burdens on the Department disproportionate to the benefit of enforcement.

Accordingly, the regulatory actions, promulgated through the December 12, 2016 final rules, 81 FR 89393, namely, the additions of 45 CFR 75.101(f), 75.300(c) and (d), 75.414(c)(1)(i) through (iii), and 75.477, and the amendments to 45 CFR 75.110(a), 75.305(a), 75.365, and 75.414(f), will not be enforced pending repromulgation.[7]

Dated: November 1, 2019.

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Eric D. Hargan,

Deputy Secretary,

Department of Health and Human Services.

[7] Elsewhere in this issue of the Federal Register, the Department publishes a notice of proposed rulemaking to begin the process of repromulgating, as appropriate, these rules.

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