



AMERICAN BENEFITS COUNCIL

September 16, 2020

Submitted via www.regulations.gov

Department of Health and Human Services
200 Independence Avenue SW
Room 713F
Washington, DC 20201

**Re: Proposed Regulations Regarding Department of Health and Human Services
Good Guidance Practices (RIN 0991-AC17)**

Dear Sir or Madam,

I write on behalf of the American Benefits Council (“the Council”) to provide comments in connection with the Department of Health and Human Services (HHS) Good Guidance Practices proposed regulations (“proposed regulations”), published in the Federal Register on August 20, 2020, by HHS. The proposed regulations, which were issued in response to Executive Order 13891, Promoting the Rule of Law Through Improved Agency Guidance Documents (“the executive order”), address requirements for the issuance and use of guidance documents, rules regarding a guidance repository and procedures for the public to petition for review of guidance. The executive order requires all federal agencies to issue similar rules, including other agencies, like HHS, that routinely issue guidance relevant to employers, employees and employee benefits.¹ As such, while the Council’s comment focuses on the HHS proposed regulations, due to the vital nature of guidance in offering and administering employee benefits, we have also considered regulations issued in response to the executive order by other relevant agencies in developing these comments.

The Council is dedicated to protecting employer-sponsored benefit plans. The Council represents more major employers – over 220 of the world’s largest corporations – than any

¹ See, e.g., Department of Labor (DOL) final regulation Promoting Openness Through Good Guidance (PRO Good Guidance), 85 FR 53163 (Aug. 28, 2020) <https://www.govinfo.gov/content/pkg/FR-2020-08-28/pdf/2020-18500.pdf>; Pension Benefit Guaranty Corporation (PBGC) final regulation Procedures for PBGC Guidance Documents, 85 FR 52481 (Aug. 26, 2020) <https://www.govinfo.gov/content/pkg/FR-2020-08-26/pdf/2020-17952.pdf>. Although the Treasury Department has not yet issued related guidance, see the Treasury Department’s guidance documents website at <https://home.treasury.gov/guidance>.

other association that exclusively advocates on the full range of employee benefit issues. Members also include organizations supporting employers of all sizes. Collectively, Council members directly sponsor or support health and retirement plans covering virtually all Americans participating in employer-sponsored programs.

We appreciate the Administration’s efforts, through the executive order and the responding regulations, to attempt to improve the guidance process, and we agree with the general principle which underlies these efforts, which, as well-described by the U.S. Department of Labor (DOL) is that “guidance should provide clarity about existing rights and obligations and help stakeholders comply with laws and regulations, not create new obligations or modify the law.”² We also understand that the Administration is concerned, as expressed in the executive order, about “inappropriate” attempts by federal agencies to regulate the public without following rulemaking procedures and about insufficient notice to regulated parties of guidance documents. At the same time, we emphasize that clear and timely guidance is invaluable for employers in offering and administering employee benefit plans, including group health plans over which HHS has joint interpretive jurisdiction with DOL and the Treasury Department (collectively, the “tri-agencies”) for many key provisions.

Employee benefits laws and regulations, which go through the formal notice and comment process, are obviously the key components that employers look to in offering employee benefits and in addressing compliance questions and issues. However, sub-regulatory guidance which the agencies may issue more quickly, in particular on discrete issues not clearly addressed by the law or regulations, is essential in creating a level playing field and providing the certainty that employers and employees need. For example, the tri-agencies have issued hundreds of frequently asked questions (FAQs) in implementing the Affordable Care Act (“ACA FAQs”), as well as FAQs to implement the mental health parity requirements that apply to group health plans (“mental health parity FAQs”).³ More recently, the tri-agencies issued a number of FAQs to clarify and answer questions regarding various provisions of the COVID-19 response legislation and to provide temporary enforcement relief on a number of group health plan related issues.⁴ This guidance is generally issued in response to requests from stakeholders, including oftentimes the Council, who consolidate and elevate key questions and issues to the federal agencies on an ongoing basis. On that note, we greatly appreciate the

² See DOL fact sheet entitled “DOL’s PRO Good Guidance Rule” at <https://www.dol.gov/sites/dolgov/files/OASP/PRO%20Good%20Guidance%20Rule%208-20.pdf>.

³ See Affordable Care Act Implementation Frequently Asked Questions at <https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/aca-implementation-faqs>.

⁴ See FAQs About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 42 & Part 43, at <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-42.pdf> and <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-43.pdf>.

responsiveness and attention of HHS and the other agencies to the issues that we raise, including during the current crisis.

As a backdrop to the more specific comments offered below, we want to highlight that putting aside the merits or favorability of any particular piece of guidance, the ability of federal agencies to continue to issue guidance quickly and clearly, as appropriate, is essential and should be preserved. In addition, the extensive guidance issued to date is relied upon by employers and employees. To the extent the HHS regulations, or the regulations issued by any other agency in response to the executive order, change the effect or application of previously issued guidance, those changes must be made clear to all stakeholders in order to provide transparency in what is required.

As to the specific proposed regulations at issue, the Council very much appreciates that HHS has provided the opportunity to comment, especially considering that the proposed regulations are intended to highlight the importance of following rulemaking procedures. The Council encourages other agencies which have not yet issued regulations in response to the executive order to give stakeholders an opportunity to comment as well.

Below we offer a number of specific comments addressing the need to preserve the ability of the agencies to issue time-sensitive guidance and the importance of coordination among the tri-agencies on the guidance process. We also request additional clarity and provide suggestions to address concerns that have arisen regarding the possible rescission of guidance, the new guidance repository and the new process allowing petitions for review of guidance.

TIME-SENSITIVE SIGNIFICANT GUIDANCE

In addition to setting out general content requirements for all guidance documents, the proposed regulations include additional requirements that apply to guidance deemed “significant”, as defined under the executive order. This generally includes guidance that can reasonably be anticipated to lead to an annual effect on the economy of \$100 million or more, guidance that creates serious inconsistencies with other rules and guidance that raises novel legal or policy issues. The requirements for the issuance of significant guidance documents include that HHS must submit the guidance document to the White House Office of Management and Budget (OMB) before it is issued, provide at least a 30-day comment period, publish a public response to major concerns raised during the comment period, and comply with applicable requirements for significant regulatory actions (e.g., regulatory impact analysis if applicable).

The proposed regulations provide an exception from the comment period requirement if HHS for good cause finds “that notice and public comment are impracticable, unnecessary, or contrary to the public interest.” As to the other requirements for significant guidance documents, exceptions can be applied if HHS and OMB “agree that exigency, safety, health, or other compelling cause warrants the exemption.”

We note that the requirements that apply to the issuance of significant guidance documents will add substantial time to the guidance process. Although we support the opportunity for stakeholders to comment and we understand that a robust guidance process supports high quality, clear guidance, we also note that in some cases guidance is needed more quickly than the full process laid out in the proposed regulations would allow. In particular, time-sensitive guidance is often needed when a new law passes which is effective immediately or very soon after enactment, such as various provisions of the ACA and COVID-19 response legislation, and in the event of a crisis, such as the COVID-19 pandemic and related economic crisis. As such, we support the provision of the proposed regulations which allows for exceptions to the time-intensive portions of the guidance process and we encourage HHS and OMB to apply those exceptions consistently and reasonably based on the elements set out in the proposed regulations.

We understand, as HHS states in the preamble to the proposed regulations, “that only a subset of guidance documents would satisfy this proposed rule’s definition of significant guidance document. This is because to qualify as guidance, as opposed to a legislative rule, a document must reflect, implement, interpret, or describe a legal obligation imposed by a pre-existing, external source or advise the public prospectively of the manner in which the agency intends to exercise a discretionary power.” Accordingly, “[i]t is HHS’s presumption that a guidance document that HHS deems significant is actually a legislative rule that must go through notice-and-comment rulemaking.” Moreover, we also expect that many guidance documents which may be needed, for example, in response to a new law or a crisis, would not be considered significant and so would be able to be issued quickly. Nonetheless, for the potentially small universe of documents which are both considered guidance and significant, the ability for HHS to issue that guidance quickly, in certain situations, will be important and the exceptions provided in the proposed regulations should be retained.

Further, we are supportive of the fact that significant guidance that is issued by HHS under a process that includes exceptions doesn’t automatically lapse at a specified time, although HHS presumably has the ability to impose a time limit on specific guidance as it deems appropriate. We understand that under the final rules issued by the DOL in response to the executive order, significant DOL guidance issued with process exemptions is “treated as temporary and will be rescinded by operation of law 270 days after it is published.” See 29 CFR § 89.6(f). As DOL explains, this “guarantees that all significant guidance eventually benefits from the notice and comment process” and that “[t]he Department expects taking comment on such guidance may be particularly valuable due to the public having had experience with it for an extended period of time”.⁵ As DOL notes, we can see the value in providing a subsequent opportunity for notice and comment on significant guidance that is, in the first instance, issued quickly and without the full process. But we also anticipate that there will be circumstances where the need for certainty and predictability support application of the guidance longer-term. As such, we

⁵ See 85 Fed. Reg. 53163, 53169 (Aug. 28, 2020).

support the approach taken in the HHS proposed regulations which is flexible and allows the agency to react to exigent and unique circumstances as needed.

CONSISTENCY ACROSS AGENCIES

For group health plans, guidance is often issued by the tri-agencies, as they have joint jurisdiction over many parallel key provisions that apply to those plans under the Employee Retirement Income Security Act (ERISA), the Public Health Service Act (PHS Act) and the Internal Revenue Code (“Code”). Under Section 104 of the Health Insurance Portability and Accountability Act (HIPAA), the tri-agencies must coordinate policies with respect to these shared provisions, and the tri-agencies operate under a Memorandum of Understanding (MOU)⁶ implementing HIPAA Section 104 which provides that the shared provisions must be administered so as to have the same effect at all times and the tri-agencies must coordinate policies relating to enforcing the shared provisions in order to avoid duplication of enforcement efforts and to assign priorities in enforcement.

As to the regulations in response to the executive order, while the DOL regulations include language which indicates DOL can modify its approach as needed regarding joint guidance (see 29 CFR § 89.3(b)), HHS instead provides that “[a]ny guidance document issued in conjunction with one or more other agencies would nonetheless be required to comply with all requirements that would be applicable if the guidance document were issued solely by HHS.”

Differences between tri-agency guidance process rules and the impact on the shared provisions are not only inconsistent with HIPAA Section 104 and the MOU but also will cause confusion, uncertainty and inefficiency. Therefore, discrepancies should be eliminated. Some discrepancies already exist (for example, as noted above, significant DOL guidance issued without the full required process will lapse at a particular time and HHS guidance will not necessarily), and other discrepancies may arise over time in application of the rules, for example regarding comment period lengths and significance determinations.

Both to support sound policy and compliance with the MOU, it is essential that the tri-agencies work to create consistent guidance procedures and to apply the procedures consistently. As such, in the final regulations, we ask that HHS acknowledge these issues and take into account that it may need to modify its approach to the guidance procedures when issuing joint guidance, to the extent a different agency has different procedures. Although DOL has already issued straight-to-final rules and Treasury has not yet issued rules in response to the executive order, we encourage the tri-agencies to continue to work together to harmonize the guidance procedures for tri-agency guidance and to apply those procedures in a consistent manner.

⁶ See 64 Fed. Reg. 70164 (Dec. 15, 1999).

RESCINDED DOCUMENTS AND GUIDANCE REPOSITORY

In addition to providing guidance procedures, the executive order and the proposed regulations require that agencies, including HHS, maintain a guidance repository on their websites, to address concerns about insufficient notice of guidance documents and to ensure all regulated parties are aware of guidance documents. More specifically, the proposed regulations provide that by November 16, 2020, HHS will maintain a guidance repository on its website and “if the Department does not include a guidance document in the guidance repository by November 16, 2020, the guidance shall be considered rescinded.” The proposed regulations provide that the HHS webpage must state that HHS “may not cite, use, or rely on any agency guidance that is not posted on the guidance repository, except to establish historical facts” and that “any guidance document previously issued by the Department is no longer in effect, and will be considered rescinded, if it is not included in the guidance repository.”

Further, interested parties may petition HHS to withdraw guidance, on an ongoing basis. And as to reinstatement of rescinded documents, the proposed regulations provide HHS may reinstate a rescinded guidance document “only by complying with all of the requirements applicable to guidance documents issued after November 16, 2020.” The proposed regulations don’t include a process for stakeholders to request that a rescinded document be reinstated.

While we generally support efforts to make guidance documents more easily obtainable and searchable, a number of significant questions and issues have arisen on this aspect of the proposed regulations, both substantive and process related.

Clearer guidance is needed on the substantive effect of a document being rescinded. Does that mean that HHS will no longer use the document in its enforcement efforts? Does it mean stakeholders can no longer rely on the document and should change their behavior? Stakeholders will be better able to determine the effect and impact of a rescission if the reason for the rescission is made clear. For example, was it merely duplicative of other, more formal guidance? Did it no longer reflect the agency’s views? Was it intended to be rescinded in part vs in whole? On this topic, concerns have arisen that historical guidance documents may simply disappear in the future without sufficient explanation for why or to what extent it was rescinded, which will cause a great deal of confusion and inefficiency.

To avoid such an outcome, we request that the final regulations include additional discussion on the different bases for rescission and the effect of rescission, including by providing examples of documents that are being rescinded, and why. We also request that when a document is rescinded, in whole or in part, that HHS (and other agencies as applicable) provide specific information at the time of rescission explaining why the document is being rescinded and the impact of the rescission.

Without a better understanding of which documents HHS and the other agencies have decided to rescind, and the bases for rescission, it is difficult to evaluate and identify all the issues that rescission may raise, and we will continue to monitor both the general process and the specific documents rescinded. However, in general, we wish to emphasize that employers and employees rely on the vast amounts of guidance issued by HHS and the other agencies. We encourage HHS and other agencies to keep the importance of and reliance on guidance in mind in deciding what to rescind and in developing and providing transparency in the rescission process. In addition, we ask that HHS and other agencies confirm that if a rescission has a substantive effect, that effect will be prospective only, that stakeholders will not be penalized for historical reliance on the guidance, and that stakeholders will be given sufficient time to make changes required by the rescission, if necessary.

Questions have also arisen regarding identification of specific documents that have been rescinded in the process of creating the repository. As we understand, in that process, the agencies have decided not to include certain documents and therefore they are considered rescinded. For example, DOL has issued a fact sheet indicating it rescinded nearly 3,200 guidance documents (approximately 12,000 pages), but it doesn't appear that a list of those documents is publicly available.⁷ It is unclear what HHS's plans are regarding identification of specific documents that are rescinded in the process of creating the document repository.

Rather than relying on absence from the repository as a signal, it is essential that HHS and other agencies make public a list of all specific documents that were rescinded in the process of creating the document repository (and as noted above, that the agencies indicate why each document is rescinded). It is practically impossible for stakeholders to reverse engineer the process and create a list of rescinded documents on their own – this would require a review of all guidance ever issued compared to the guidance included in the repository, which, for example, for HHS currently includes over 22,000 documents. Without such a list provided by the agencies, stakeholders have no way of knowing what specific documents have been rescinded, which will obviously cause extensive confusion and inefficiency and undermine the goals of the executive order and proposed regulations. In fact, for agencies that have already created their repositories we have heard about confusion caused by the inability to find guidance on the repository website, which gives rise to questions about whether that means the document can still be relied upon. These issues can be addressed with a clear list of documents that have been rescinded, which also identifies the reason for the rescission and the effect of the rescission.

The same substantive and process concerns exist regarding identification of rescinded documents going forward (i.e., documents that are rescinded after the repository is created under the provision in the proposed regulations allowing interested parties to petition for guidance to be withdrawn). It appears that DOL plans to issue a list of added and

⁷ See DOL fact sheet entitled “DOL’s PRO Good Guidance Rule” at <https://www.dol.gov/sites/dolgov/files/OASP/PRO%20Good%20Guidance%20Rule%208-20.pdf>.

rescinded documents each quarter (29 CFR § 89.4(f)), but the HHS proposed regulations do not address this issue. We request that all agencies keep permanent, frequently-updated lists of added and rescinded documents on an ongoing basis and that the list identify the reason for the rescission and the effect of the rescission. We request this be provided as a separate list, rather than solely as an identifier in the database that is part of the search function or filter, due to concerns about the size of the database and issues with the search functions and any given individual's ability to successfully search and obtain a particular document.

Further, due to the extensive number of documents HHS is presumably working to populate in the repository, it seems possible, if not likely, that some documents may inadvertently not be included by the November 16th deadline – not because they were deemed rescinded but because there was an administrative or technical mishap. We request that the final regulations take this possibility into account and allow documents that were accidentally excluded from the repository by the deadline to be restored, without a complicated process, once they have been identified.

In addition, consistent with our comments above, we emphasize the need for the tri-agencies to work together to ensure that the rules regarding rescissions of tri-agency guidance are consistent and are clearly and affirmatively communicated to stakeholders and are consistently applied.

Lastly, on a more practical point, we note that over the years, stakeholders, including Council members, have become accustomed to finding relevant guidance on certain webpages (e.g., the list of ACA FAQs). We request that HHS (and the tri-agencies) separately maintain guidance on the relevant, substantive webpage, where it has historically been found, to avoid confusion and questions, even if that same guidance is also populated in the repository. In addition, we suggest that the substantive website where the guidance has historically been found also include signifiers showing that the guidance is still applicable, with a link to the repository, or, if applicable, indicating that the document has been rescinded, with a link to the rescission list/explanation.

PETITION FOR REVIEW

The proposed regulations, consistent with the executive order, set out procedures which allow interested parties to petition HHS to withdraw or modify particular guidance. We are generally supportive of HHS and other agencies providing stakeholders the chance to provide feedback and raise issues with regard to guidance, and we acknowledge that the ability to petition HHS and other agencies, as set out in the proposed regulations, could prove valuable in a number of circumstances. At the same time, the ability for stakeholders to, on an ongoing basis, petition for removal or modification of guidance could undermine the certainty provided by guidance and in some cases add confusion and burden for stakeholders, in particular in light of the resources often required to implement

guidance. We ask that HHS and the other relevant agencies keep these various considerations in mind in implementing this aspect of the regulations.

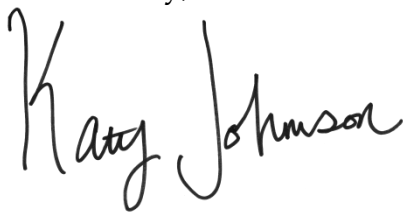
More specifically, while the proposed regulations provide that responses to withdrawal and modification petitions will be published on the webpage, it isn't clear whether petitions will be made public. We ask that the petitions be made public at the time submitted, and easily found, to allow for other stakeholders to weigh in as necessary. In addition, we request clarification as to whether guidance which has gone through a notice and comment process can be effectively overturned through the petition process, which seems inconsistent with the spirit of the executive order and the proposed regulations. We also ask that HHS confirm that, absent special circumstances, during the 90 day period when it is considering a request for removal or modification, the guidance will continue to apply.

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Thank you for the opportunity to comment on these proposed regulations. We appreciate the Administration's efforts to improve the guidance process and also thank the Administration for being responsive to questions and issues raised by the Council and our employer members with regard to employee benefit plans, through the guidance process. We reiterate the need to avoid undermining the essential role that guidance plays in providing clarity and certainty for employers as they offer and operate benefit plans for millions of Americans. We appreciate your attention to these comments among the many other essential matters before you.

If you have any questions or would like to discuss these recommendations further, please contact us at (202) 289-6700.

Sincerely,

A handwritten signature in black ink that reads "Katy Johnson". The signature is written in a cursive, flowing style.

Katy Johnson
Senior Counsel, Health Policy