

I. Background

The Office for Civil Rights (OCR) at the Department of Health and Human Services (HHS) is responsible for enforcing certain regulations issued under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and the Health Information Technology for Economic and Clinical Health (HITECH) Act, to protect the privacy and security of protected health information (PHI), namely, the HIPAA Privacy, Security, and Breach Notification Rules (the HIPAA Rules).

The HIPAA Privacy Rule permits a business associate of a HIPAA covered entity to use and disclose PHI to conduct certain activities or functions on behalf of the covered entity, or provide certain services to or for the covered entity, but only pursuant to the explicit terms of a business associate contract or other written agreement or arrangement under 45 CFR 164.502(e)(2) (collectively, “business associate agreement” or BAA), or as required by law.

Federal public health authorities and health oversight agencies, state and local health departments, and state emergency operations centers have requested PHI from HIPAA business associates (*i.e.*, a disclosure of PHI), or requested that business associates perform public health data analytics on such PHI (*i.e.*, a use of PHI by the business associate) for the purpose of ensuring the health and safety of the public during the COVID-19 national emergency, which also constitutes a nationwide public health emergency. Some HIPAA business associates have been unable to timely participate in these efforts because their BAAs do not expressly permit them to make such uses and disclosures of PHI.

II. Parameters and Conditions of Enforcement Discretion

To facilitate uses and disclosures for public health and health oversight activities during this nationwide public health emergency, effective immediately, OCR will exercise its enforcement discretion and will not impose penalties against a business associate or covered entity under the Privacy Rule provisions 45 CFR 164.502(a)(3), 45 CFR 164.502(e)(2), 45 CFR 164.504(e)(1) and (5) if, and only if:

- the business associate makes a good faith use or disclosure of the covered entity’s PHI for public health activities consistent with 45 CFR 164.512(b), or

cause to issue this guidance without prior public comment and without a delayed effective date. 5 U.S.C. 553(b)(B) & (d)(3).

health oversight activities consistent with 45 CFR 164.512(d); and

- The business associate informs the covered entity within ten (10) calendar days after the use or disclosure occurs (or commences, with respect to uses or disclosures that will repeat over time).

Examples of such good faith uses or disclosures covered by this Notification include uses and disclosures for or to:

- the Centers for Disease Control and Prevention (CDC), or a similar public health authority at the state level, for the purpose of preventing or controlling the spread of COVID-19, consistent with 45 CFR 164.512(b).

- The Centers for Medicare and Medicaid Services (CMS), or a similar health oversight agency at the state level, for the purpose of overseeing and providing assistance for the health care system as it relates to the COVID-19 response, consistent with 45 CFR 164.512(d).

This enforcement discretion does not extend to other requirements or prohibitions under the Privacy Rule, nor to any obligations under the HIPAA Security and Breach Notification Rules applicable to business associates and covered entities. For example, business associates remain liable for complying with the Security Rule’s requirements to implement safeguards to maintain the confidentiality, integrity, and availability of electronic PHI (ePHI), including by ensuring secure transmission of ePHI to the public health authority or health oversight agency. This Notification does not address other federal or state laws (including breach of contract claims) that might apply to the uses and disclosures of this information.

III. Collection of Information Requirements

This notice of enforcement discretion creates no legal obligations and no legal rights. Because this notice imposes no information collection requirements, it need not be reviewed by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Roger T. Severino,

Director, Office for Civil Rights, Department of Health and Human Services.

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DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 555

[Docket No. NHTSA-2018-0103]

Denial of Petition for Reconsideration; Temporary Exemption From Motor Vehicle Safety and Bumper Standards

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Denial of petition for reconsideration.

SUMMARY: This document denies a petition for reconsideration submitted by Advocates for Highway and Auto Safety, Center for Auto Safety, Consumer Reports, Consumer Federation of America, and Ms. Joan Claybrook (collectively, the “Petitioners”) of a final rule amending NHTSA’s regulation on temporary exemption from the Federal Motor Vehicle Safety Standards (FMVSS). The final rule eliminated the provision calling for the agency to determine that an application for a temporary exemption from any FMVSS or bumper standard or for a renewal of exemption is complete before the agency publishes a notification summarizing the application and soliciting public comments on it.

DATES: April 7, 2020.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

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This document denies a petition for reconsideration submitted by the Petitioners requesting reconsideration of a December 26, 2018 final rule (83 FR 66158) amending NHTSA’s regulation on temporary exemption from the FMVSS. The intended effect of the final rule was to solicit public comments on a petition more quickly than had been

the case under part 555 prior to the change in procedure.

I. Background

The National Traffic and Motor Vehicle Safety Act (Safety Act), as amended, authorizes the Secretary of Transportation to exempt, on a temporary basis, under specified circumstances, and on terms the Secretary deems appropriate, motor vehicles from an FMVSS or bumper standard. This authority is set forth at 49 U.S.C. 30113. The Secretary has delegated the authority for implementing this section to NHTSA.¹

In exercising this authority, NHTSA must look comprehensively at the request for exemption and find that an exemption would be consistent with the public interest and with the objectives of the Safety Act.² In addition, the Secretary must make at least one of the following more-focused findings, which NHTSA commonly refers to as the “basis” for the exemption:

(i) compliance with the standard[s] [from which exemption is sought] would cause substantial economic hardship to a manufacturer that has tried to comply with the standard[s] in good faith;

(ii) the exemption would make easier the development or field evaluation of a new motor vehicle safety feature providing a safety level at least equal to the safety level of the standard;

(iii) the exemption would make the development or field evaluation of a low-emission motor vehicle easier and would not unreasonably lower the safety level of that vehicle; or

(iv) compliance with the standard would prevent the manufacturer from selling a motor vehicle with an overall safety level at least equal to the overall safety level of nonexempt vehicles.³

Per the Safety Act, once NHTSA receives a petition for an exemption, the agency is required to publish a notice of receipt of the petition and provide the public the opportunity to comment. However, NHTSA does have a certain amount of discretion to set procedural rules regarding time and way in which a petition is filed, as well as the contents of the petition.⁴

NHTSA's procedural regulations implementing these statutory requirements are codified at 49 CFR part 555, “Temporary Exemption from Motor Vehicle Safety and Bumper Standards.” Per the requirements in 49 CFR 555.5, a petition for a temporary exemption must, among other things, provide supporting documentation that would

enable NHTSA to make the findings required to grant the exemption under one of the four exemption bases. In addition, the petition must also explain why the exemption would be in the public interest and consistent with the objectives of the Safety Act. NHTSA's procedures for processing exemption petitions once they are received are described in 49 CFR 555.7.

The final rule made no changes to the ability of the public to comment on a published petition for exemption, nor to the substantive requirements for a petition. The opportunity for the public to comment on a petition remains the same today as it has always been: The agency publishes a notification in the **Federal Register** summarizing the application and inviting public comment on whether the application should be granted or denied. Before NHTSA issued its December 26, 2018, final rule (83 FR 66158), however, this **Federal Register** notification would only be published after the agency determined that the application was complete (*i.e.*, that the application included all the information required under 49 U.S.C. 30113 and 49 CFR part 555). However, if NHTSA found that the application was incomplete, NHTSA informed the applicant, pointed out the areas of insufficiency, and stated that the application would not receive further consideration until the required information was submitted. Prior to the final rule, the agency would not make the application available to the public and request public comment at this stage in the process unless the additional required information was submitted. Only then would the agency publish the notification requesting public comment.

Importantly, the final rule did not amend 49 CFR 555.7(d) or (e), which describe what steps NHTSA must take after the agency determines whether an exemption petition contains “adequate justification” to grant the petition. 49 CFR 555.7(d) states that, if NHTSA determines that the application does not contain adequate justification to grant an exemption after considering the application and the public comments, the Administrator denies the petition and notifies the petitioner in writing. 49 CFR 555.7(e) states that, if the Administrator determines that the application does contain adequate justification to grant the petition, the Administrator grants the petition and notifies the applicant in writing. Under both cases, the Administrator also publishes a notification in the **Federal Register** stating the decision to grant or deny the petition, and the reasons for the decision.

The December 26, 2018 final rule amended 49 CFR 555.7 by eliminating the provision stating that the agency will not publish a notice of receipt of an exemption petition to solicit public comments prior to making a determination that the petition is “complete.”⁵ As was noted in the final rule, the reason for this was NHTSA's difficulty in differentiating between incomplete petitions (for which, prior to the final rule, a notice of receipt would not be published) and petitions which were complete, but which failed to provide adequate justification to grant (for which, prior to the final rule, a notice of receipt would be published). This was especially the case in the context of complex petitions involving new or innovative vehicle designs, which has in the past led to delays in processing these petitions.⁶ This final rule did not change the substantive requirements that exemption petitions must meet; the amended regulation continues to provide that the agency will determine whether an application for exemption contains adequate justification in deciding whether to grant or deny the application.⁷

II. Petition for Reconsideration and Agency Response

The Petitioners submitted a petition for reconsideration requesting that NHTSA stay the effective date of the December 26, 2018 final rule, and to proceed with a new notice of proposed rulemaking along with a notice and comment period.

First, the Petitioners argue that by issuing the final rule, NHTSA did not follow its direct final rulemaking procedures for amendments that involve complex or controversial issues because, pursuant to 49 CFR 553.14, direct final rules may not be issued when they are likely to result in “adverse public comment.” The Petitioners argue that the final rule would have resulted in adverse public comments because the new procedure is controversial among the Petitioners. (Under NHTSA's direct final rulemaking procedures, if NHTSA receives an adverse comment after issuing a direct final rule, the agency must withdraw the rule and issue an NPRM proposing the amendment.)

Second, the Petitioners argue that, if the agency did not intend for the final rule to be a direct final rule, the agency violated the Administrative Procedure Act's (APA) notice and comment requirement because the agency did not issue an NPRM proposing the change.

¹ 49 CFR 1.94

² 49 U.S.C. 30113(b)(3)(A).

³ 49 U.S.C. 30113(b)(3)(B).

⁴ 49 U.S.C. 30113(b)(2).

⁵ 83 FR 66158 (Dec. 26, 2018).

⁶ *Id.*

⁷ *Id.*

Third, the Petitioners argue that the final rule is not in the public interest because it deprives the public of the opportunity to “review issues of great importance to safety” and permits the agency to publish incomplete applications. The Petitioners believe that the regulatory change would impose additional burdens on the public because to fully evaluate an incomplete application and its implications on safety, the public would be required to conduct independent research and investigation to obtain missing information not contained in an incomplete application.

Finally, the Petitioners argue that NHTSA has not put forth data or evidence to show that the requirement of waiting until an application is complete before publication has caused an undue delay or hardship on any applicant, the agency, or the public.

A. This Final Rule was Not Issued as a Direct Final Rule Under 49 CFR 553.14

The Petitioners’ assumption that NHTSA intended for this rulemaking to be considered a direct final rule, subject to 49 CFR 553.14, is incorrect. The APA includes two circumstances when notice and comment rulemaking procedures do not apply: (1) “to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or” (2) “when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. 553(b). As described below, this rule falls into the first exception, as a rule of agency procedure. NHTSA’s direct final rulemaking regulation is primarily directed at the second exception, as it requires a threshold “good cause” finding. See 49 CFR 553.14.

In any event, the procedures in 49 CFR 553.14 are not mandatory. 49 CFR 553.14 states that if the Administrator makes a “good cause” finding, “a direct final rule *may* [emphasis added] be issued” according to the direct final rulemaking procedures. Likewise, it provides that: “[r]ules that the Administrator judges to be non-controversial and unlikely to result in adverse public comment *may* [emphasis added] be published as direct final rules,”⁸ thereby giving NHTSA discretion to publish a rule according to the specified “direct final rule” procedures. NHTSA did not purport to issue the final rule that is the subject of

this petition according to those procedures. The petitioned final rule did not refer to 49 CFR 553.14 and instead expressly indicated that it was issued without notice and comment pursuant to the APA exception for procedural rules in 5 U.S.C. 553(b)(3)(A).⁹ Petitioners do not support their claim that NHTSA somehow acted “in violation of” its discretionary direct final rulemaking procedures in 49 CFR 553.14, when the agency instead applied a statutory exception in the APA.

B. Immediate Adoption of a Rule Under the APA

NHTSA fully complied with the APA when it issued a final rule for immediate adoption without a notice and comment period. Section 553(b)(3)(A) of the APA (U.S.C., Title 5) provides that notice and comment procedures do not apply to rules of agency organization, procedure, or practice, except when notice or hearing is required by *statute*. Under this section, an agency may issue a final rule without seeking comment prior to the rulemaking. Procedural rules are agency provisions that are primarily directed toward improving the efficient and effective operations of an agency, not toward the determination of the rights or interests of affected parties.¹⁰ A rule that simply prescribes the manner in which the parties present themselves or their viewpoints to the agency does not alter the underlying rights or interests of the parties.¹¹

The purpose of the petitioned final rule is to expedite the publishing of documents soliciting public comment on exemption applications,¹² which is directly related to improving the efficient and effective operations of the agency. It amended a provision of NHTSA’s regulations concerning the agency’s “[p]rocessing of applications.”¹³ The final rule simply eliminated the provision calling for the agency to determine that an application for exemption is complete before publishing a notification summarizing an application and soliciting public comments on it, which is a prescription of the manner in which applicants present themselves to the agency. Therefore, this procedural final rule is not directed toward the determination

of the rights or interests of the Petitioners as the Petitioners’ public interest argument seems to suggest; it does not alter the underlying rights or interest of interested parties.

Petitioners’ assertion that the final rule “contravenes NHTSA’s notice-and-comment obligations under the Administrative Procedure Act” is unpersuasive. NHTSA expressly found that the final rule met the exception in APA section 553(b)(3)(A) because “[t]he sole purpose of this rule is to eliminate the provision calling for the agency to determine that a petition is complete before the agency publishes a notification summarizing the petition and soliciting public comments on it. This rule does not impose any additional requirements on exemption applicants or the public. Therefore, NHTSA has determined that notice and public comment are unnecessary.”¹⁴ Petitioners provided no explanation for why they believe notice-and-comment procedures apply notwithstanding the APA exception cited by the agency in the final rule.

C. Advantages of Removing Completeness Determination Requirement

Contrary to the assertion by Petitioners, the subject final rule is in the public’s interest for several reasons. First, the final rule increases transparency by giving the public the opportunity to thoroughly review exemption applications that otherwise may not have been disclosed to the public or subject to public input. Under the prior rule, NHTSA first had to make a threshold finding before opening a public docket on the petition. If NHTSA found that the application was incomplete, NHTSA informed the applicant, pointed out the areas of insufficiency, and stated that the application would not receive further consideration until the required information was submitted. The public did not have the opportunity to review the incomplete application. Under the amended rule, the public can review incomplete exemption applications.

Second, under the final rule, both the agency and the public can comprehensively evaluate applications for exemption. Prior to the final rule, only the agency would make a completeness determination, without input on that issue from the public. The final rule increases the public’s opportunity to evaluate the application and provide input because the agency will decide whether to grant an exemption application, complete or not,

⁸ 83 FR 66158, 66159.

⁹ *Clarian Health West, LLC v. Burwell*, 206 F. Supp. 3d 393, 414 (D.D.C. 2016), *rev’d on other grounds*, *Clarian Health West, LLC v. Hagan*, 878 F.3d 346 (DC Cir. 2017).

¹⁰ *Inova Alexandria Hospital v. Shalala*, 244 F.3d 342, 349 (2001).

¹¹ 83 FR 66158 (Dec. 26, 2018).

¹² See revised heading of 49 CFR 555.7.

¹³ 83 FR 66158, 66159—60.

based on the application *and* the public comments. Among its comments, the public can submit opinions as to whether the application is complete. The public gets to see an application sooner as opposed to not seeing it until NHTSA makes a threshold

completeness determination. The public can point out what it sees as insufficiencies to the agency; and if the agency agrees, the application will be denied unless it is later supplemented. If an application is supplemented, the public will have access to any supplemental information to the same extent as if the supplement happened before the application became public under the old rule. In addition, the public can, if it so chooses, comment on completeness, or on any other supplemental information submitted through the public comment process.

Finally, the final rule does not impose additional requirements on the public to perform research, as the Petitioners claimed without support. Although published exemption applications may be incomplete, NHTSA is still required to make an “adequate justification” determination based on the information provided by the applicant. An application that lacks merit or critical information will be denied, based on public input and the agency’s analysis, regardless of whether there is a threshold completeness determination. A determination that an application is complete is not a determination that the application should be granted. If NHTSA determines that the application does not contain “adequate justification,” the Administrator denies it and notifies the applicant in writing, pointing out the areas of insufficiency.¹⁵ It is not the public’s duty to perform research to determine areas of insufficiency. The Administrator also publishes in the **Federal Register** a notification of the denial and the reasons for it, which is available to the public. Further, if a member of the public believes the agency’s explanation for granting an application lacks sufficient supporting arguments and facts, he or she may seek to have the agency reconsider the grant.

D. NHTSA Provided a Reasoned Justification for the Amendment

NHTSA articulated the purpose behind changing this procedural rule in the preamble to the rule. Specifically, NHTSA changed its procedure “to expedite the publishing of documents soliciting public comment on exemption petitions.”¹⁶ Petitioners’ argument that

“NHTSA has put forth no data or evidence in the Final Rule that the current requirement of waiting until the application is complete before publishing it in the **Federal Register** has caused undue delay or hardship on any applicant, the agency, or the public” lacks merit. NHTSA provided a reasoned explanation of its change in procedure. *See F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). NHTSA explained how the prior procedure led to delays.¹⁷ The agency also explained that the prior procedure was unnecessary under the statute, particularly in light of the substantive determination it will continue to make regarding whether a petition contains an adequate justification.¹⁸ Petitioners’ assertions regarding the public interest have not convinced the agency that it should return to its prior procedure, which would reduce transparency and delay the ability of the public to obtain and comment on exemption applications.

III. Conclusion

For the reasons discussed above, the agency is denying the Petitioners’ petition for reconsideration of the December 26, 2018 final rule (83 FR 66158).

Issued in Washington, DC, under authority delegated in 49 CFR 1.95 and 501.4.

James Clayton Owens,
Acting Administrator.

[FR Doc. 2020-06403 Filed 4-6-20; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 200124-0029; RTID 0648-XS030]

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; 2020 Red Snapper Private Angling Component Closures in Federal Waters off Texas

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS announces closures for the 2020 fishing season for the red snapper private angling component in

the exclusive economic zone (EEZ) off Texas in the Gulf of Mexico (Gulf) through this temporary rule. The red snapper recreational private angling component in the Gulf EEZ off Texas closes on April 1, 2020 until 12:01 a.m., local time, on June 1, 2020, and will close again at 12:01 a.m., local time, on August 3, 2020 until 12:01 a.m., local time, on January 1, 2021. This closure is necessary to prevent the private angling component from exceeding the Texas regional management area annual catch limit (ACL) and to prevent overfishing of the Gulf red snapper resource.

DATES: This closure is effective on April 1, 2020 until 12:01 a.m., local time, on June 1, 2020, then closes again at 12:01 a.m., local time, on August 3, 2020 until 12:01 a.m., local time, on January 1, 2021.

FOR FURTHER INFORMATION CONTACT:

Susan Gerhart, NMFS Southeast Regional Office, telephone: 727-824-5305, email: susan.gerhart@noaa.gov.

SUPPLEMENTARY INFORMATION: The Gulf reef fish fishery, which includes red snapper, is managed under the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP). The FMP was prepared by the Gulf of Mexico Fishery Management Council and is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

The final rule implementing Amendment 40 to the FMP established two components within the recreational sector fishing for Gulf red snapper: the private angling component, and the Federal for-hire component (80 FR 22422, April 22, 2015). Amendment 40 also allocated the red snapper recreational ACL (recreational quota) between the components and established separate seasonal closures for the two components. On February 6, 2020, NMFS implemented Amendments 50 A-F to the FMP, which delegated authority to the Gulf states (Louisiana, Mississippi, Alabama, Florida, and Texas) to establish specific management measures for the harvest of red snapper in Federal waters of the Gulf by the private angling component of the recreational sector (85 FR 6819, February 6, 2020). These amendments allocate a portion of the private angling ACL to each state, and each state is required to constrain landings to its allocation.

As described at 50 CFR 622.23(c), a Gulf state with an active delegation may request that NMFS close all, or an area of, Federal waters off that state to the

¹⁵ 49 CFR 555.7(d).

¹⁶ 83 FR 66158, 66159.

¹⁷ *Id.*

¹⁸ *Id.*