described in paragraph (a)(1) of this section.

(b) *End of the period.* The MCIT pathway for a breakthrough device ends as follows:

(1) No later than 4 years from the date the breakthrough device received FDA market authorization.

(2) Prior to 4 years if a manufacturer withdraws the breakthrough device from the MCIT pathway.

(3) Prior to 4 years if the breakthrough device becomes the subject of a national coverage determination or otherwise becomes noncovered through law, regulation, or at the discretion of the Secretary subsequent to an FDA medical device safety communication or Warning Letter.

(4) Prior to 4 years if the FDA removes authorization of a device, the breakthrough device is removed from the MCIT pathway.

Dated: December 31, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: January 5, 2021.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–00707 Filed 1–12–21; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 1

[HHS–OS–2021–0001]

RIN 0991–AC18

Department of Health and Human Services Transparency and Fairness in Civil Administrative Enforcement Actions

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services is issuing regulations promoting transparency and fairness in civil enforcement actions. These regulations will help to ensure that regulated parties receive fair notice of laws and regulations they are subject to, and have an opportunity to contest an agency determination prior to the agency taking an action that has a legal consequence.

DATES: Effective January 12, 2021.

FOR FURTHER INFORMATION CONTACT: Brenna Jenny, Department of Health and Human Services, 200 Independence Avenue SW, Room 713F, Washington, DC 20201. Email: *Good.Guidance@hhs.gov.* Telephone: (202) 690–7741.

I. Statutory and Regulatory Background

The primary legal authority supporting this rulemaking is 5 U.S.C. 301. That provision provides that the ''head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property.'' This statute authorizes an ''agency to regulate its own affairs,'' and issue rules, such as this one, that are ''rules of agency organization[,] procedure or practice.'' *Chrysler Corp.* v. *Brown,* 441 U.S. 281, 309–10 (1979). Similarly, 42 U.S.C. 1302 provides that the Secretary ''shall make and publish such rules and regulations, not inconsistent with this chapter, as may be necessary to the efficient administration of the functions with which [he] is charged'' under Chapter 7 of the Social Security Act. Chapter 7 contains, among other things, statutory provisions governing Medicare, Medicaid, and the Health Insurance Portability and Accountability Act (HIPAA).

The Administrative Procedure Act (''APA''), 5 U.S.C. 551 *et seq.,* specifies the process by which such regulations are promulgated. Department heads generally must prescribe regulations through notice-and-comment rulemaking, but there is an exception for ''rules of agency organization, procedure, or practice.'' The requirements for notice and comment prior to finalization also do not apply to regulations that involve ''a matter relating to agency management or personnel.'' 5 U.S.C. 553(a)(2).

Because this final rule only specifies procedures that agency personnel must follow or that will govern civil enforcement actions, it is exempt from the requirement for notice and comment prior to finalization. In determining whether notice-and-comment rulemaking is required, the ''critical feature is that [the rule] covers agency actions that do not themselves alter the rights or interests of the parties, although it may alter the manner in which the parties present themselves or their viewpoints to the agency.'' *Nat'l Sec. Counselors* v. *CIA,* 931 F. Supp. 2d 77, 106–07 (D.D.C. 2013) (quoting *Batterton* v. *Marshall,* 648 F.2d 694, 707 (D.C. Cir. 1980)). This rule is exempt from notice and comment because it does not ''put[ ] a stamp of approval or disapproval on a given type of behavior.'' *Am. Hosp. Assoc.* v. *Bowen,* 834 F.2d 1037, 1047 (D.C. Cir. 1987). What had been a regulatory violation prior to finalization of this rule still is; the Department of Health and Human Services (''HHS'' or ''the Department'') is only modifying the procedures governing civil enforcement actions and the Department's civil enforcement action practices. To be sure, these procedural modifications, like most rules of agency procedure or personnel, might have some impact on the public. But agency rules that impose ''derivative,'' ''incidental,'' or ''mechanical'' burdens upon regulated individuals are considered procedural, rather than substantive, and are therefore exempt from the notice-and-comment requirement. *Id.* at 1051. Moreover, to the extent this rule has effects on the public, it only provides additional protections to the public, rather than depriving the public of any rights or interests it previously had.

The APA requires that ''administrative policies affecting individual rights and obligations be promulgated pursuant to certain stated procedures so as to avoid the inherently arbitrary nature of unpublished *ad hoc* determinations.'' *Morton* v. *Ruiz,* 415 U.S. 199, 232 (1974). The Freedom of Information Act amended the APA to advance this goal, and generally requires that agencies publish in the **Federal Register** their substantive rules of general applicability, statements of general policy, and interpretations of law that are generally applicable. 5 U.S.C. 552(a)(1)(D). Unless a party has actual and timely notice of the terms of a rule or policy, the Freedom of Information Act generally provides that a party may not be adversely affected by a rule or policy required to be published in the **Federal Register** that is not so published. 5 U.S.C. 552(a)(1)(flush language). This rule of agency procedure ensures that HHS actions comport with these requirements.

II. Summary of Transparency and Fairness Regulations

To provide regulated parties with greater transparency and fairness in administrative actions, and consistent with the requirements of Executive Order 13892 of October 9, 2019, ''Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication,'' 84 FR 55239 (Oct. 15, 2019), HHS is setting forth policies that promote transparency and fairness in civil enforcement actions that will apply to all divisions of HHS. The requirements in this rule amend 45 CFR part 1.

This rule is one component of the Department's broader regulatory reform initiative. The rule is designed to ensure accountability, fairness of how the Department uses guidance, proper use of guidance documents, and opportunities for third parties to be heard, and to safeguard the important principles underlying the United States administrative law system.

A. Scope (45 CFR 1.1)

The requirements established pursuant to this rule in §§ 1.2(b) and 1.6 through 1.9 apply to civil enforcement actions by any component of the Department. Sections 1.3 through 1.5 (as well as the definitions in § 1.2 that were added through the Good Guidance Practices final rule at 85 FR 78770 (Dec. 7, 2020), and that we will recodify in this rule at § 1.2(a)) will continue to apply to all guidance documents until FDA amends its good guidance practices regulation to be consistent with the HHS Good Guidance Practices rule, at which point §§ 1.2(a) and 1.3 through 1.5 shall apply to all divisions of HHS except FDA.

Nothing in this rule shall apply:

- To any action that pertains to foreign or military affairs, or to a national security or homeland security function of the United States (other than procurement actions and actions involving the import or export of nondefense articles and services);
- To any action related to a criminal investigation or prosecution, including undercover operations, or any civil enforcement action or related investigation by the Department of Justice, including any action related to a civil investigative demand under 18 U.S.C. 1968;
- To any action related to detention, seizure, or destruction of counterfeit goods, pirated goods, or other goods that infringe intellectual property rights;
- To any investigation of misconduct by an agency employee or any disciplinary, corrective, or employment action taken against an agency employee; or
- In any other circumstance or proceeding to which application of this order, or any part of this order, would, in the judgment of the Secretary of HHS, undermine the national security.

B. Definitions (45 CFR 1.2)

The definitions section at 45 CFR 1.2 is amended to include the following definitions at paragraph (b).

Civil Enforcement Action

HHS defines ''civil enforcement action'' to mean an action with legal consequence taken by the Department based on an alleged violation of the law. Such actions include administrative enforcement proceedings and enforcement adjudication (which is the administrative process undertaken by any component of the Department to resolve the legal rights and obligations of specific parties with regard to a particular enforcement issue pending before it) but do not include actions taken in the normal course of the Department's regulatory communications or decision-making, for example, decisions on product applications (such as approvals or denials/withdrawals of approval), claims authorizations, responses to citizen petitions, food or color additive petitions, or public health notifications.

Legal Consequence

HHS defines ''legal consequence'' as the result of an action that directly or indirectly affects substantive legal rights or obligations including by subjecting a regulated party to potential liability in an enforcement action. The meaning of this term is informed by the Supreme Court's discussion in *U.S. Army Corps of Engineers* v. *Hawkes Co.,* 136 S. Ct. 1807, 1813–16 (2016), and includes, for example, agency letters or orders establishing or increasing the probability of liability for regulated parties in a subsequent enforcement action, *Ipsen Biopharmaceuticals, Inc.* v. *Azar,* 943 F.3d 953, 956 (D.C. Cir. 2019); *Rhea Lana, Inc.* v. *Dep't of Labor,* 824 F.3d 1023, 1030 (D.C. Cir. 2016). It does not include a warning letter or other communication, such as one describing inspectional observations, that pursuant to agency policy is intended to provide notice to a regulated party and elicit voluntary compliance. Such warning letters and inspectional observations have no immediate regulatory implications for the entity, are an interim step in the agency's compliance communications with an entity, and are not final agency action that has legal consequences for a party. *See Orton Motor, Inc.* v. *HHS,* 884 F.3d 1205, 1215 (D.C. Cir. 2018); *Holistic Candlers & Consumers Ass'n* v. *FDA,* 664 F.3d 940 (D.C. Cir. 2012); *see also Hi-Tech Pharm., Inc.* v. *Hahn,* Civ. No. 19–1268(RBW), 2020 WL 3498588, *5 (D.D.C. June 29, 2020); *Lystn, LLC* v. *FDA,* No. 19–cv–1943–PAB–KLM, 2020 WL 248962, *5 (D. Colo. Jan. 16, 2020); *Cody Labs., Inc.* v. *Sebelius,* No. 10–CV–00147–ABJ, 2010 WL 3119279, *11 (D. Wyo. July 26, 2010), *aff'd,* 446 F. App'x 964, 969 (10th Cir. 2011); *Gomperts* v. *Azar,* No. 1:19–cv–00345–DCN, 2020 WL 3963864, *4–5 (D. Idaho July 13, 2020).

Unfair Surprise

HHS defines ''unfair surprise'' to mean a lack of reasonable certainty or fair warning, from the perspective of a reasonably prudent member of regulated industry, of what a legal standard administered by an agency requires, or the initiation of litigation by HHS following ''a very lengthy period of conspicuous inaction,'' in other words deliberate inaction, suggesting the agency previously had a different interpretation. *Christopher* v. *SmithKline Beecham Corp.,* 567 U.S. 142, 156 (2012). However, an agency does not create unfair surprise when it proceeds with a new interpretation that it established in notice-and-comment rulemaking. *See Martin* v. *Occupational Safety & Health Review Comm'n,* 499 U.S. 144, 158 (1991) (identifying ''adequacy of notice to regulated parties'' as one factor relevant to the reasonableness of the agency's interpretation).

The definitions currently at 45 CFR 1.2 will be moved into a new paragraph (a). All definitions at paragraph (a) apply to all components of HHS until FDA amends its good guidance practices regulation, at which point the definitions at 45 CFR 1.2(a) shall apply to all divisions of HHS except FDA. The definitions at § 1.2(b) will apply to all components of the Department, including FDA.

C. Proper Department Reliance on Guidance Documents (45 CFR 1.6)

This rule reiterates the application of certain existing legal principles to HHS's use of guidance documents: When the Department takes a civil enforcement action or otherwise makes a determination based on an alleged violation of law that has legal consequence for a person or state, it must allege or establish the violation of law by applying statutes or regulations. HHS may not use guidance documents to impose binding requirements or prohibitions on persons outside of the executive branch except as authorized by law or expressly incorporated into a contract. Noncompliance with a standard or practice that is not in a statute or regulation and announced solely in a guidance document may not be treated as itself a violation of applicable statutes or regulations, unless expressly authorized by statute.

This rule also explains the appropriate circumstances when the Department may use a guidance document in civil enforcement actions. The Department may use a guidance document to explain the legal applicability of a statute or regulation

with regard to prohibition of conduct, but when it does so, HHS may only use the guidance document to articulate the Department's understanding of how a statute or regulation applies to particular circumstances. Except when referring to a guidance document for historical facts, the Department may reference a guidance document in a civil enforcement action only if it has notified the public of such document to convey that understanding in advance. The Department must notify the public in advance of a guidance document through publication in the Department's guidance repository (as described in § 1.4 and available at *hhs.gov/guidance*).

D. Fairness and Notice in Civil Enforcement Actions and Administrative Inspections (45 CFR 1.7)

This rule would require the Department to only apply standards or practices that have been publicly stated in a manner that would not cause unfair surprise when HHS takes a civil enforcement action or otherwise makes a determination based on an alleged violation of law that has legal consequence for a person or state, unless a statutory exception applies. *See, e.g.,* 42 U.S.C. 1395hh(e). For purposes of this regulation, the Department would consider standards or practices to be publicly stated if available in paper publications or on the internet.

HHS avoids unfair surprise not only when it imposes penalties but also whenever it adjudges past conduct to have violated the law. For example, the Department generally cannot retroactively impose liability on a party for conduct that violates a new agency interpretation. *But see* 42 U.S.C. 1395hh(e). The Department also may not alter its interpretation during an adjudicative proceeding if doing so would impose new liability on parties who have acted in good faith on the prior interpretation. *SmithKline Beecham,* 567 U.S. at 156 & n.15.

Section 7 of Executive Order 13892 requires that each agency that conducts civil administrative inspections must publish a rule of agency procedure governing such inspections, if such a rule does not already exist. The Department is adding a requirement at 45 CFR 1.7 that HHS shall only conduct civil administrative inspections according to published rules of agency procedure. While the Administrative Procedure Act exempts these subsequently issued rules of agency procedure themselves from notice-and-comment rulemaking, *see* 5 U.S.C. 553(b)(3)(A), each agency must make the rules governing its civil administrative inspections, including audits, publicly available and readily accessible, such as by posting them on a website.

E. Fairness and Notice in Jurisdictional Determinations (45 CFR 1.8)

The requirement for fairness and notice also extends to jurisdictional determinations. If the Department relies on a decision previously issued by an agency within the Department in an agency adjudication (*i.e.,* proceedings before and decided by the agency), administrative order, or agency document to assert a new or expanded claim of jurisdiction (*e.g.,* a claim to regulate a new subject matter or a new basis for liability, or a relinquishment of a claim of jurisdiction), the Department must give fair notice by publishing the initial decision in the **Federal Register** or the Department's guidance repository. *See* 45 CFR 1.4. The Department should not rely on the new claim of jurisdiction to take a civil enforcement action regarding conduct that occurred before such publication. A claim of jurisdiction is not ''new or expanded'' simply because it involves a new or novel set of facts so long as it is based on an established principle of general applicability.

If the Department intends to rely on a document arising out of litigation (other than a publicly published opinion of an adjudicator) such as a brief, a consent decree, or a settlement agreement, to establish jurisdiction in future civil enforcement actions involving persons who were not parties to the litigation, the Department must also publish that document in the **Federal Register** or on the Department's guidance repository. Alongside publication of the document, the Department must also provide an explanation of the document's jurisdictional implications. Publication of a document discussed in this paragraph may either be in full or by citation, if the document is publicly available.

HHS is also proposing that if the Department seeks judicial deference to its interpretation of a document arising out of litigation (other than a publicly published opinion of an adjudicator) in order to establish a new or expanded claim of jurisdiction, HHS must, before seeking judicial deference, publish the document or a notice of availability in the **Federal Register** or on the Department's guidance repository, along with an explanation of the document's jurisdictional implications.

F. Opportunity To Contest Agency Determinations (45 CFR 1.9)

Providing regulated parties with the opportunity to be heard, including through informal oral or written communications, prior to the Department taking any civil enforcement action that has legal consequence is critical to ensuring that the Department operates with transparency and fairness. This rule will require that, before any component of the Department takes any civil enforcement action with respect to a particular entity that has legal consequence for that entity—including by issuing to such a person a notice of noncompliance or other similar notice that has immediate regulatory consequence or the immediate effect of subjecting the person to potential liability—the Department must afford that person an opportunity to be heard, either orally or in writing, as deemed appropriate at the Department's election. The rule will require HHS to provide the person with its proposed legal and factual determinations and then give the person a reasonable amount of time to respond to those determinations. The specific timeframe shall be in the discretion of the agency but must be long enough to provide a meaningful opportunity to be heard. Certain circumstances may warrant a time period of 30 days, while other circumstances may warrant a shorter period, such as 15 days or fewer, particularly where existing agency procedures already offer a shorter period in which to respond. Unless the Department withdraws the action, the Department must then respond in writing to the regulated party and articulate the final basis for the Department's action. This written response may be issued contemporaneous to the Department taking the action with legal consequence. We anticipate that generally, existing HHS procedures will already satisfy these standards, and where they do, those existing procedures will continue in effect unchanged. This rulemaking is not intended to preempt existing rules of agency procedure that are already consistent with this rule. Furthermore, where the Department takes an action based on a predicate finding that was reached following notice, an opportunity to be heard, and a written response, for example, where the Department revokes Medicare enrollment based on a prior exclusion or felony conviction, these procedural requirements are considered to have already been satisfied.

These procedures regarding fair notice and an opportunity to respond would not apply where the agency, in its discretion, determines there is a serious threat to health, safety, or similar emergency, or where a statute specifically authorizes proceedings that are inconsistent with this section, including proceedings without a prior opportunity to be heard. Where such a threat arises and a statute does not specifically authorize proceedings without a prior opportunity to be heard, HHS would still provide an affected entity with an opportunity to be heard and a written response as soon as practicable. In this context, a serious threat means that, as reasonably determined by the Department, there is a non-negligible likelihood of the threat materializing.

We anticipate that the exception from § 1.9 for actions taken in the context of threats to health, safety, or similar emergencies will apply broadly to public health agencies acting in furtherance of their missions. Actions will be considered to fall into this exception regardless of whether there is a showing of actual, imminent risk or harm, either to persons or animals. The agency has sole discretion to determine when an action falls into this exception. An agency may invoke this exception regardless of whether agency action is taken reactively (*e.g.,* to address an unsafe item currently on the market) or proactively (*e.g.,* to enforce regulations needed to protect public health prior to actual exposure by the public to unsafe items). Actions that fall into this exception include, for example, enforcing age restrictions or other controls around access to certain regulated products, enforcing manufacturer recordkeeping or reporting requirements, enforcing premarket requirements where there is an absence of or insufficient data concerning the product, protecting beneficiary data privacy or a federal healthcare program beneficiary from harm, and taking action to remove unapproved, misbranded, or adulterated human or animal products from the market.

Because of this exception, the procedures in § 1.9 generally will not impact, for example, the administrative detention process for foods, drugs, devices, and tobacco products (21 U.S.C. 334(g), (h)), the detention, refusal, and where authorized, destruction of imported products regulated by FDA (21 U.S.C. 381), disqualification (21 CFR parts 56, 58, 312, 511, 812), administrative detention, recall requests, import alerts, or other public notifications about food, drug, device, or tobacco products, or other actions related to investigating adulterated or misbranded products.

These procedures would also not apply to settlement negotiations between agencies and regulated parties, to notices of a prospective legal action, where a statute specifically precludes review of agency action, or to litigation before courts. Examples of situations where statutes specifically authorize differently structured proceedings include, but are not limited to, the hospital cost report appeals process (42 U.S.C. 1395oo), the individual benefit claims appeals process (42 U.S.C. 1395ff), and the process for the review of disallowances of Medicaid expenditures by the Secretary (42 U.S.C. 1316(e)). In such circumstances, the process and substantive standards governing review of claims arising under a relevant statute or regulation remain governed by those more specific procedures. The procedures would also not apply to any action related to a criminal investigation or prosecution, including undercover operations that may be used in a criminal investigation or prosecution, or any civil enforcement action either related to an investigation by the Department of Justice, or referred to the Department of Justice.

III. Rulemaking Analyses and Notices

A. Executive Orders 12866 and 13563

Executive Order 12866, ''Regulatory Planning and Review,'' and Executive Order 13563, ''Improving Regulation and Regulatory Review,'' direct agencies to assess all costs and benefits of available regulatory alternatives and, if the regulation is necessary, to select regulatory approaches that maximize net benefits. The Department does not believe that this rulemaking is a significant regulatory action under these Executive Orders. This rule describes an update to the Department's current processes to ensure that it operates with transparency and fairness. The requirements in 45 CFR 1.6 through 1.9 relating to the proper use of guidance documents and fairness and notice in enforcement actions generally already exist in law. The requirements set forth in Section 6 of Executive Order 13892 and codified at 45 CFR 1.6 may exceed the requirements imposed by the Due Process clause of the Constitution and may impose a burden by delaying the time until HHS can take actions with legal consequence. However, this process will also offer important procedural safeguards and potentially reduce economic costs borne by regulated entities, which will have an opportunity to respond in writing before the Department takes an action that has (potentially costly) legal consequence.

The Department anticipates that the public, and, in particular, regulated parties, would benefit from greater efficiencies and more transparency in how the Department regulates, including facilitating smoother operations within HHS by clearly defining how guidance can be used.

B. Executive Order 13771

This final rule is neither a regulatory nor a deregulatory action under Executive Order 13771, ''Reducing Regulation and Controlling Regulatory Costs,'' 82 FR 9339 (Feb. 3, 2017), because this rule is estimated to impose no more than de minimis costs on regulated entities.

C. Regulatory Flexibility Act

The Department has examined the economic implications of this rule as required by the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.* The RFA requires an agency to describe the impact of a rulemaking on small entities by providing an initial regulatory flexibility analysis, unless the agency expects that the rule will not have a significant impact on a substantial number of small entities, provides a factual basis for this determination, and proposes to certify the statement. 5 U.S.C. 603(a), 605(b). The Department considers a proposed or final rule to have a significant impact on a substantial number of small entities if it has at least a three percent impact on revenue on at least five percent of small entities. The Department anticipates that this rule will allow small entities to operate more efficiently, by increasing the transparency of government regulation. As a result, the Department has determined, and the Secretary certifies, that this final rule would not have a significant impact on the operations of a substantial number of small entities.

D. Executive Order 13132 (Federalism)

Executive Order 13132, ''Federalism,'' establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments or has Federalism implications. The Department has determined that this final rule will not impose such costs or have any federalism implications.

E. Paperwork Reduction Act of 1995

In accordance with the Paperwork Reduction Act of 1995 and its implementing regulations, 44 U.S.C. 3501–3521; 5 CFR part 1320, the

Department has reviewed this rule and has determined that it imposes no new collections of information.

List of Subjects in 45 CFR Part 1

Guidance, Government employess.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR Part I as set forth below:

PART 1—TRANSPARENCY AND FAIRNESS IN CIVIL ADMINISTRATIVE ENFORCEMENT AND ADJUDICATION

■ 1. The authority citation for part 1 continues to read as follows:

Authority: 42 U.S.C. 1302, 5 U.S.C. 301, 551 *et seq.*

■ 2. Section 1.1 is revised to read as follows:

§ 1.1 Scope.

Sections 1.2(a) and 1.3 through 1.5 of this part shall apply to guidance documents issued by all components of the Department, until the Secretary amends the Food and Drug Administration's good guidance regulations at 21 CFR 10.115 to bring them into conformance with the requirements of this part, at which point, such amended regulations shall apply to the Food and Drug Administration, and §§ 1.2(a) and 1.3 through 1.5 shall apply to all divisions of the Department except the Food and Drug Administration. Sections 1.2(b) and 1.6 through 1.9 of this part shall apply to all components of the Department.

■ 3. Section 1.2 is amended by designating the existing text as paragraph (a) followed by the alphabetical ordered definitions, revising newly designated paragraph (a) introductory text, and adding paragraph (b).

The revision and addition read as follows:

§ 1.2 Definitions.

(a) The following definitions apply to all components of the Department until the Secretary amends the Food and Drug Administration's good guidance regulations at 21 CFR 10.115 to bring them into conformance with the requirements of §§ 1.3 through 1.5 of this part:

* * * * *

(b) The following definitions apply to all components of the Department:

Civil enforcement action means an action with legal consequence taken by the Department based on an alleged violation of the law. Such actions include administrative enforcement proceedings and enforcement adjudication (which is the administrative process undertaken by any component of the Department to resolve the legal rights and obligations of specific parties with regard to a particular enforcement issue pending before it) but do not include actions taken in the normal course of the Department's regulatory communications or decision-making, for example, decisions on product applications (such as approvals, denials, or withdrawals of approval), claims authorizations, citizen petitions, food or color additive petitions, or public health notifications.

Legal consequence means the result of an action that directly or indirectly affects substantive legal rights or obligations, including by subjecting a regulated party to potential liability in an enforcement action. This includes agency letters or orders establishing greater liability for regulated parties in a subsequent enforcement action, but excludes communications that have no immediate regulatory implications for a person or entity, such as letters (*e.g.,* warning letters) or inspectional observations that serve as an interim step in the agency's compliance communications with a person or entity or that are intended to encourage voluntary compliance.

Unfair surprise means a lack of reasonable certainty or fair warning, from the perspective of a reasonably prudent member of regulated industry, of what a legal standard administered by an agency requires.

■ 4. Section 1.6 is added to read as follows:

§ 1.6 Proper Department reliance on guidance documents.

(a) *Overview.* A civil enforcement action must have an appropriate legal basis. When the Department takes a civil enforcement action or makes a determination based on an alleged violation of law that has legal consequence for a person or state, it must allege or establish the violation of law by applying statutes or regulations.

(b) *Limitations on the use of guidance documents.* (1) The Department may not use guidance documents to impose binding requirements or prohibitions on persons outside the executive branch except as expressly authorized by law or as expressly incorporated into a contract.

(2) The Department may not treat noncompliance with a standard or practice announced solely in a guidance document as itself a violation of applicable statutes or regulations except as expressly authorized by law.

(3) If the Department uses a guidance document to explain the legal applicability of a statute or regulation, that document can do no more, with respect to prohibition of conduct, than articulate the Department's understanding of how a statute or regulation applies to particular circumstances.

(4) The Department may cite to a guidance document in a civil enforcement action only if it has notified the public of such document in advance through publication, in the Department's guidance repository, as described in § 1.4.

■ 5. Section 1.7 is added to read as follows:

§ 1.7 Fairness and notice in civil enforcement actions and administrative inspections.

(a) When the Department takes a civil enforcement action, the Department may only apply standards or practices that have been publicly stated in a manner that would not cause unfair surprise.

(b) The Department must avoid unfair surprise when it imposes penalties and whenever it adjudges past conduct to have violated the law.

(c) The Department shall only conduct civil administrative inspections according to published rules of agency procedure.

■ 6. Section 1.8 is added to read as follows:

§ 1.8 Fairness and notice in jurisdictional determinations.

(a) If the Department relies on a decision in an agency adjudication, administrative order, or agency document to assert a new or expanded claim of jurisdiction (*e.g.,* a claim to regulate a new subject matter or a new basis for liability, or a relinquishment of a claim of jurisdiction), the Department must give fair notice by publishing the initial decision before the conduct over which jurisdiction is sought occurs. It must publish the initial decision in full or by citation, if publicly available, in the **Federal Register** or the Department's guidance repository described in § 1.4. A claim of jurisdiction is not ''new or expanded'' simply because it involves a new or novel set of facts so long as it is based on an established principle of general applicability.

(b) If the Department intends to rely on a document arising out of litigation (other than a publicly published opinion of an adjudicator), such as a brief, a consent decree, or a settlement agreement, to establish jurisdiction in future civil enforcement actions

involving persons who were not parties to the litigation, the Department must—

(1) Publish that document, either in full or by citation if publicly available, in the **Federal Register** or on the Department's guidance repository described in § 1.4, and

(2) Publish an explanation of the document's jurisdictional implications.

(c) Before seeking judicial deference to the Department's interpretation of a document arising out of litigation (other than a publicly published opinion of an adjudicator) in order to establish a new or expanded claim of jurisdiction in a different case, the Department must—

(1) Publish the document or a notice of availability in the **Federal Register** or on the Department's guidance repository described in § 1.4, and

(2) Publish an explanation of the document's jurisdictional implications.

■ 7. Section 1.9 is added to read as follows:

§ 1.9 Opportunity to contest agency determination.

(a) *Departmental overview.* Except as provided in paragraph (c) of this section, prior to the Department taking any civil enforcement action with respect to a particular entity that has legal consequence for that entity, including by issuing to such a person a notice of noncompliance, or other similar notice that has immediate regulatory consequence, but excluding communications that have no immediate regulatory implications for the entity, such as those that serve as an interim step in the agency's compliance communications with the entity or that are intended to encourage voluntary compliance, the Department shall provide—

(1) Written notice to the affected entity of the initial legal and factual determinations underpinning the initial adverse determination;

(2) An opportunity for the affected entity to respond in writing and, if determined appropriate by the Department, orally; and

(3) A written response from the Department to the affected entity after receiving a timely request from the affected entity under paragraph (a)(2) of this section.

(b) *Timing and content of written responses.* (1) The Department will select a meaningful amount of time in which the affected entity must submit a written response to the Department. This writing must be submitted within the time period specified by the Department, unless the Department concludes an extension is warranted, and state the reasons for the entity's disagreement with the Department's proposed action for purposes of requiring a response in accordance with paragraph (a)(3) of this section.

(2) The Department's written response must respond to the affected entity and articulate the basis for its final decision. This written response may be issued contemporaneous to the Department taking the action with legal consequence.

(c) *Exceptions.* The procedures in paragraphs (a) and (b) of this section do not apply where the Department, in its discretion, determines there is a serious threat to health, safety, or similar emergency, or where a statute specifically authorizes proceeding without a prior opportunity to be heard. In such event, HHS would still provide an affected entity with an opportunity to be heard and a written response as soon as practicable. The procedures in paragraphs (a) and (b) do not apply to settlement negotiations between agencies and regulated parties, to notices of a prospective legal action, to litigation before courts, or any action related to a criminal investigation or prosecution, including undercover operations that may be used in a criminal investigation or prosecution, or any civil enforcement action either related to an investigation by the Department of Justice, or referred to the Department of Justice.

Dated: January 7, 2021.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–00592 Filed 1–12–21; 4:15 pm]

BILLING CODE 4150–26–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 20–340; RM–11865; DA 20–1425; FRS 17287]

Television Broadcasting Services; Minneapolis, Minnesota.

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Media Bureau, Video Division (Bureau) has before it a Notice of Proposed Rulemaking issued in response to a petition for rulemaking filed by Multimedia Holdings Corporation (Multimedia), licensee of KARE, channel 11, Minneapolis, Minnesota, requesting the substitution of channel 31 for channel 11 at Minneapolis in the DTV Table of Allotments. The Bureau had instituted a freeze on the acceptance of rulemaking petitions by full power television stations requesting channel substitutions in May 2011 and waived the freeze to consider Multimedia's proposal to substitute channel 31 at Minneapolis. TEGNA, Inc., filed comments in support of the petition reaffirming its commitment to applying for channel 31. The Bureau believes the public interest would be served by the substitution and will permit the station to better serve its viewers, who have experienced reception problems with VHF channel 11.

DATES: Effective January 14, 2021.

FOR FURTHER INFORMATION CONTACT: Joyce Bernstein, Media Bureau, at *Joyce.Bernstein@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order,* MB Docket No. 20–340; RM–11865; DA 20–1425, adopted December 2, 2020, and released December 2, 2020. The full text of this document is available for download at *https://www.fcc.gov/edocs.* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to this proceeding.

The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

Final Rule

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows: