

DEPARTMENT OF JUSTICE

Executive Office for Immigration Review

8 CFR Parts 1003 and 1292

[EOIR Docket No. 159; AG Order No. 4478–2019]

RIN 1125–AA58

Board of Immigration Appeals: Affirmance Without Opinion, Referral for Panel Review, and Publication of Decisions as Precedents**AGENCY:** Executive Office for Immigration Review, Department of Justice.**ACTION:** Final rule.

SUMMARY: The Department of Justice (Department) is publishing this final rule (“final rule” or “rule”) to amend the regulations regarding the administrative review procedures of the Board of Immigration Appeals (BIA or Board). This final rule sets forth the Department’s longstanding position that the regulations providing for an affirmance without opinion (AWO), a single-member opinion, or a three-member panel opinion are not intended to create any substantive right to a particular manner of review or decision. The final rule also clarifies that the BIA is presumed to have considered all of the parties’ relevant issues and claims of error on appeal regardless of the type of the BIA’s decision, and that the parties are obligated to raise issues and exhaust claims of error before the BIA. In addition, the final rule codifies standards for the BIA’s consideration in evaluating whether to designate particular decisions as precedents. Finally, the final rule provides clarity surrounding precedent decisions in the context of decisions from the Executive Office for Immigration Review (EOIR) regarding the recognition of organizations and the designation of accredited representatives.

DATES: This rule is effective September 3, 2019.**FOR FURTHER INFORMATION CONTACT:** Lauren Alder Reid, Assistant Director, Office of Policy, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2616, Falls Church, Virginia 22041; telephone (703) 305–0289 (not a toll-free call).**SUPPLEMENTARY INFORMATION:****I. Public Participation**

The Department published a proposed rule with request for comments in the **Federal Register** in June 2008. See *Board of Immigration Appeals:*

Affirmance Without Opinion, Referral for Panel Review, and Publication of Decisions as Precedents, 73 FR 34654 (June 18, 2008). At the conclusion of the comment period on August 18, 2008, three public interest law and advocacy groups; two law professors; a law student and a recent law school graduate; and one non-attorney had submitted six sets of comments. Because some comments overlapped, and because other commenters covered multiple topics, the comments are addressed summarily by topic in Section III, *infra*.

II. Introduction*A. Background*

On October 18, 1999, the Department published a final rule authorizing a single BIA member to affirm the decision of an immigration judge by a summary written order without issuing a separate written opinion. See *Executive Office for Immigration Review; Board of Immigration Appeals: Streamlining*, 64 FR 56135 (Oct. 18, 1999). The written order used for this purpose is commonly referred to as an affirmance without opinion (AWO). The AWO contains only two sentences, both prescribed by regulation, without any additional language or explanation for the affirmance. Under the relevant regulations, the AWO states: “The Board affirms, without opinion, the result of the decision below [*i.e.*, the decision of the immigration judge or the Department of Homeland Security (DHS) officer that was appealed to the BIA]. The decision below is, therefore, the final agency determination. See 8 CFR 3.1(a)(7).”¹ See 8 CFR 1003.1(e)(4)(ii).²

In 2002, the Department published a final rule that, while maintaining the basic AWO process, mandated the use of an AWO in any case that met the regulatory threshold criteria. See *Board of Immigration Appeals: Procedural Reforms To Improve Case Management*, 67 FR 54878 (Aug. 26, 2002). Compare 8 CFR 3.1(a)(7)(ii) (2000) (providing that a single BIA member “may” affirm without opinion), with 8 CFR 1003.1(e)(4) (2003)³ (providing that a

¹ The text later changed to cite to 8 CFR 3.1(e)(4). See 67 FR at 54903.

² The background discussion accompanying the proposed rule published in the current rulemaking proceeding contains an account of the history and use of AWOs. 73 FR at 34655–57.

³ In 2003, the Attorney General redesignated the previous regulations in 8 CFR part 3, relating to EOIR, as 8 CFR part 1003 in connection with the abolition of the former Immigration and Naturalization Service and the transfer of its responsibilities to DHS. See *Aliens and Nationality; Homeland Security; Reorganization of Regulations*, 68 FR 9824 (Feb. 28, 2003). Under the Homeland

single BIA member “shall” affirm without opinion).

Under the 2002 rule, an AWO is issued if the BIA member concludes that “the result reached in the decision under review was correct,” that any errors in the decision were “harmless or nonmaterial,” and that either the issues on appeal are “squarely controlled” by precedent and do not present a novel factual scenario that requires a decision to apply precedent or are not so substantial as to warrant issuance of a written opinion by the BIA. 8 CFR 1003.1(e)(4)(i) (2003).

On January 9, 2006, Attorney General Alberto Gonzales directed a comprehensive review of the immigration courts and the BIA. The Department undertook the review in response to concerns about the quality of the decisions of the immigration judges and the BIA and to reports of intemperate behavior by some immigration judges.

The review team received comments about the BIA’s streamlining process and its reform regulations. Critics of the procedural reforms rule speculated that the revised procedures allowed BIA members insufficient time to review cases thoroughly and made it more difficult for the BIA to publish adequate numbers of precedent decisions. Supporters observed that the reforms brought much-needed efficiency to the appellate process, which allowed the BIA to eliminate a large backlog of cases and to adjudicate cases in a more timely manner.

On August 9, 2006, Attorney General Gonzales announced that the review was complete and directed that EOIR implement 22 measures to improve adjudications by the immigration judges and the BIA. This final rule is one of several regulatory actions relating to that review.

B. The Proposed Regulatory Changes

The 2008 proposed rule stated that the Department had evaluated the BIA’s caseload and resources and found that “the basic principles set forth in the [2002] Board reform rule were still necessary to prevent future backlogs and delays in adjudication.” 73 FR at 34655. Thus, the proposed rule did not seek comment on whether the BIA should continue to use AWOs. *Id.* (stating that “the Department is not reopening or seeking public comment on the existing final regulations that were adopted in 2002”). Rather, the Department

Security Act, EOIR (including the BIA and the immigration judges) remains under the authority of the Attorney General. See 6 U.S.C. 521; 8 U.S.C. 1103(g).

proposed three specific adjustments that would: (1) Encourage the increased use of single-member written decisions instead of AWOs to address poor or intemperate decisions of immigration judges, (2) allow the use of three-member written decisions for the purpose of providing greater legal analysis for particularly complex cases, and (3) authorize three-member panels, by majority vote, to designate their decisions as precedent decisions. *Id.*

C. Decisions Regarding the Recognition of Organizations and the Accreditation of Representatives

At the time of the underlying proposed rule's publication, responsibility for administering EOIR's recognition and accreditation program, which recognizes organizations and authorizes accredited representatives to represent aliens in immigration proceedings before EOIR and in cases with DHS, lay with the BIA. Consequently, under its general authority to issue precedent decisions, the BIA would intermittently issue precedent decisions in cases involving recognition and accreditation issues. See, e.g., *Matter of United Farm Workers Found.*, 26 I&N Dec. 454 (BIA 2014) (addressing whether a recognized organization needs to apply for a representative's accreditation at more than one location). In 2017, responsibility for the recognition and accreditation program within EOIR was transferred from the BIA to the Office of Legal Access Programs (OLAP), but the transfer did not provide a mechanism by which EOIR could designate decisions as precedents. See *Recognition of Organizations and Accreditation of Non-Attorney Representatives*, 81 FR 92346 (Dec. 19, 2016). This rule would correct that deficiency.

III. Intent and Nature of the Regulations

In each of the respects discussed below, the Department in this rulemaking is revising the regulations to clarify the intent and nature of the regulations relating to the form of BIA decisions and the scope of the BIA's consideration of issues presented on appeal. The Department's interpretations of the intended meaning of its regulations are fully consistent with the Attorney General's authority to issue regulations and clarify the intent, purpose, and nature of those regulations. See *INS v. Stanisic*, 395 U.S. 62, 72 (1969) (quoting *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945)) (an administrative agency's interpretation of its own regulations is entitled to "controlling

weight unless it is plainly erroneous or inconsistent with the regulation"); *Matter of Armendarez-Mendez*, 24 I&N Dec. 646, 653 (BIA 2008).

With regard to the provisions of the 2008 proposed rulemaking, the Department has considered the public comments, the continuing need to maintain AWOs as a necessary resource for BIA adjudication, and the goal of securing finality in immigration cases as efficiently as possible.

With respect to one proposal outlined in the proposed rule, the Department has determined that it will not revise EOIR's regulations to provide for publication of precedent decisions by majority vote of the permanent Board members assigned to a three-member panel. Although the Department recognizes that a single member or a panel of BIA members is able to address and resolve issues in a thorough and judicious manner, the Department also recognizes that the BIA's published decisions representing the views of the majority of the *en banc* BIA are important in ensuring accuracy, consistency, uniformity, and clarity in the BIA's guidance and interpretation of relevant law and regulation. The current process better provides for the consistency of BIA case law. See *Matter of Burbano*, 20 I&N Dec. 872, 873–74 (BIA 1994). Apart from this decision regarding publication by majority vote, this final rule adopts, with changes, the regulatory amendments set forth in the proposed rule.

Finally, the Department is including a related revision to the regulations to clarify the intent to provide for the issuance of precedent decisions in the context of the recognition and accreditation program.

A. The Form of a Board Decision

The 2008 proposed rule discussed the Department's interpretation of the BIA's regulatory structure regarding the BIA's decision to issue an AWO or a single-member or three-member decision. 73 FR at 34656–57. The purpose of that discussion was to clarify that institutional concerns, which are uniquely within the BIA's expertise, may factor into the assessment of what form of decision to issue. The Department presented that discussion in regards to both the proposal to allow BIA members to exercise discretion in determining whether to issue an AWO, 73 FR at 34656, and the proposal to clarify that the regulations do not create any substantive or procedural right to a particular form of BIA decision, 73 FR at 34657.

Commenters raised several objections to the discussion in both contexts. With

regard to the BIA's discretion, the proposed rule stated that:

In determining whether to exercise its discretion to issue an AWO or a single-member opinion, the Board may consider available resources to balance the need to complete cases efficiently while evaluating whether there is a need to provide further guidance to the immigration judge, the parties, and the federal courts through a written decision addressing the issues in a case.

73 FR at 34356. The commenters who raised issues concerning this statement argued that the BIA's caseload and resources should have no bearing on what form of decision the BIA uses or whether to resolve an appeal by an AWO or other type of decision. One commenter suggested that if caseload and resources are considerations, a BIA member might use the streamlining process to "deny an immigrant's claim, rather than grant relief, on the grounds that the Board member reviewing the case simply lacked the time or inclination to spend his or her resources writing a reasoned, public opinion for that particular case."

The BIA employs a staff of attorneys, paralegals, and support personnel that prepares the cases and draft decisions for BIA member review. In particular, under the BIA's case-processing system, a staff attorney reviews a case and recommends issuance of a decision as an AWO, a single-member decision, or a three-member decision. A BIA member then decides what form of decision to issue after an independent review of the record of proceedings and consideration of the nature of the case, the issues and arguments presented by the parties in support of the appeal or motion, and prior agency decisions. The BIA member also assesses whether the regulatory criteria set forth in 8 CFR 1003.1(e)(4)(i), (e)(5), or (e)(6) require the issuance of an AWO decision, warrant a single-member decision, or warrant referral to a three-member panel for decision. Thus, a BIA member—in contrast to the commenter's suggestion—does not decide whether to issue an AWO based on whether he "lack[s] the time or inclination to spend his or her resources writing a reasoned, public opinion for that particular case."

The Department seeks to clarify that the use of an AWO does not reflect an abbreviated review of a case, but rather reflects the use of an abbreviated order to describe that review where the regulatory requirements of 8 CFR 1003.1(e)(4)(i) are met. The Department also seeks to clarify that a case before the BIA undergoes tiers of staff screening and review with a BIA member who ultimately determines

what form of decision to use.

Accordingly, the Department is satisfied that each case has undergone thorough and complete review before a determination of whether an AWO is required. This final rule retains an AWO as a mandatory form of decision to be issued in appropriate situations.

Taking into account caseload and resources in deciding what form of decision the BIA chooses to issue is not new. In 1999, Attorney General Janet Reno linked resource and caseload concerns to the form of the BIA's dispositions when she created the first AWO and single-member reforms and observed that three-member written opinions are time consuming, require significant resources, and should be used selectively. *See* 64 FR at 56136–38; *see also Matter of Burbano*, 20 I&N Dec. at 874 (recognizing that “summary treatment of a case does not mean that we have conducted an abbreviated review of the record or have failed to exercise our own discretion”). The BIA in 1998 received in excess of 28,000 new cases, and concerns about resource management have grown only more pronounced in the intervening years; in fiscal year 2018, for example, the BIA received more than 49,000 new cases.

Attorney General Reno also explained that, “[e]ven in routine cases,” the “process of screening, assigning, tracking, drafting, revising, and circulating cases is extremely time consuming.” 64 FR at 56137. In addition, she explained that “disagreements concerning the rationale or style of a draft decision can require significant time to resolve.” *Id.* Attorney General Reno concluded that the BIA should use more streamlined forms of dispositions and become selective in using three-member decisions. *Id.* The Department further stated in the 1999 rule that using streamlined forms of decisions would “allow the Board to manage its caseload in a more timely manner” and “maintain a viable appellate organization that handles an extraordinarily large caseload.” 64 FR at 56138. Similarly, in 2002, Attorney General John Ashcroft cited caseload and resource considerations as the justification for expanding the streamlining procedures to promote the issuance of AWOs and to normalize single-member decisions. *See* 67 FR at 54879. Although former Attorney General Reno's statements in the proposed rule about caseload considerations, internal resources, and layers of review pertained primarily to issuing single-member decisions instead of three-member decisions, these considerations are also relevant when a single BIA member assesses whether an

AWO would most efficiently use the BIA's limited resources in resolving an appeal.

The 2008 proposed rule expressed concern that some courts have construed the regulations to permit judicial review of the BIA's decision about what form of opinion to issue, independently of the merits of the final agency position, and that this “additional layer of review in some circuits is not consistent with the [2002] rule's goal of promoting efficiency and finality in the immigration system.” 73 FR at 34657. The proposed rule sought to address this concern by clarifying that regulations providing for an AWO, a single-member opinion, or a three-member panel opinion were intended to reflect an internal agency directive created for the purpose of efficient case management and disposition of cases pending before the BIA, and were not to be interpreted to create any substantive or procedural rights enforceable before any immigration judge, the BIA, or any court. Several commenters raised issues concerning this proposed amendment.

The commenters wrote that the agency may not eliminate an alien's “right” to review of a BIA member's judgment to issue an AWO or other form of BIA decision. The courts of appeals that have reviewed challenges to the streamlining process have uniformly concluded, however, that respondents have no constitutional or statutory right to a particular form or manner of a BIA decision. *See Zhang v. U.S. Dept. of Justice*, 362 F.3d 155, 157–58 (2d Cir. 2004); *Yuk v. Ashcroft*, 355 F.3d 1222, 1229–32 (10th Cir. 2004); *Dia v. Ashcroft*, 353 F.3d 228, 242 (3d Cir. 2003) (*en banc*); *Denko v. INS*, 351 F.3d 717, 729–30 (6th Cir. 2003); *Falcon Carrique v. Ashcroft*, 350 F.3d 845, 850–51 (9th Cir. 2003); *Khattak v. Ashcroft*, 332 F.3d 250, 252–53 (4th Cir. 2003); *Georgis v. Ashcroft*, 328 F.3d 962, 967 (7th Cir. 2003); *Mendoza v. U.S. Att'y Gen.*, 327 F.3d 1283, 1288–89 (11th Cir. 2003); *Albathani v. INS*, 318 F.3d 365, 376–77 (1st Cir. 2003). Thus, the Department is not eliminating an existing substantive right, but is simply clarifying the original intent underlying the streamlining regulation that the form of the BIA's decision should not be reviewable.

Indeed, the 2002 final rulemaking explained that there is no statutory right or law requiring a particular form of decision or method of review before the BIA. 67 FR at 54883, 54888–90. Because the BIA is established under the Attorney General's regulations, he “is free to tailor the scope and procedures of administrative review of immigration matters as a matter of discretion.” 67 FR

at 54882 (citing, *e.g.*, *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 524–25 (1978)). The 2002 final rulemaking also quoted the Supreme Court's admonition against review of certain agency matters, stating that “‘administrative agencies should be free to fashion their own rules of procedure and to pursue methods of inquiry capable of permitting them to discharge their multitudinous duties.’” *Id.* (quoting *Vermont Yankee*, 435 U.S. at 524–25 (quoting *FCC v. Pottsville Broad. Co.*, 309 U.S. 134, 143 (1940))).

Commenters also suggested that an independent review of the judgment of a single BIA member to issue an AWO is necessary to ensure the adequacy of the BIA's review. One commenter claimed that “the AWO formula . . . affirms the result reached by the Immigration Judge but expressly eschews reliance on the Immigration Judge's reasoning and affords no information concerning the BIA's reasoning in affirming the decision.” However, the immigration judge's decision becomes the final agency decision for the court's review and provides reasons for the decision that can themselves be reviewed. The 2002 final rulemaking explained that “[t]he immigration judge's order provides the rationale” for an AWO, and “[t]he Department does not believe there is any basis for believing that providing a regurgitation of the same facts and legal reasoning . . . will be beneficial to the respondent or the reviewing courts in most cases.” 67 FR at 54885–86. The 2002 final rule expressly designated the immigration judge's decision as the one to be reviewed, required standard language to that effect in each AWO, and prohibited the BIA from adding any explanation or reasoning. *See* 8 CFR 1003.1(e)(4)(ii). This prohibition pertains to a single member's reasons for affirming the immigration judge's decision. Thus, the language of the AWO itself states, “The Board affirms, without opinion, the result of the decision below. *The decision below is, therefore, the final agency determination.*” *Id.* (emphasis added).

Moreover, as several courts have already recognized, the BIA's judgment to issue an AWO is similar to the practices of several courts of appeals to issue a summary disposition, as a matter of judicial efficiency, in cases that are viewed as not raising novel or complex issues, or whose issues were adequately addressed by the lower court. *See, e.g.*, *Ngure v. Ashcroft*, 367 F.3d 975, 984–85 (8th Cir. 2004); *Blanco de Belbruno v. Ashcroft*, 362 F.3d 272, 281–82 (4th Cir. 2004); *Dia*, 353 F.3d at 240 n.7; *Soadje v. Ashcroft*, 324 F.3d 830, 832 (5th Cir.

2003); *see also* 8th Cir. R. 47B (allowing the use of an AWO if an opinion would have no precedential value and (1) fact-findings are not clearly erroneous, (2) the evidence in support of a jury verdict is not insufficient, (3) the relevant administrative order is supported by substantial evidence on the record as a whole, or (4) no error of law appears); 3d Cir. Internal Operating Procedures 10.6 (after affording parties opportunity to submit argument regarding summary action, “the court . . . may take summary action . . . if it clearly appears that no substantial question is presented or that subsequent precedent or a change in circumstances warrants such action”); 4th Cir. R. 36.3 (allowing the use of summary affirmance, following oral argument, where all judges on a panel agree that “a case would have no precedential value, and that summary disposition is otherwise appropriate”). It has never been thought that the Supreme Court would review the propriety of a court’s decision to use one of these summary dispositions, as opposed to the merits of the underlying decision, or that these sorts of summary dispositions are improper. *See Ngure*, 367 F.3d at 985.

Commenters also argued that the decision to dispose of an appeal by AWO should be reviewable as a means of resolving the “jurisdictional conundrum” that arises when a court is unable to determine, by virtue of the AWO, the extent to which the agency’s decision rests upon grounds that it may review. This objection is invalid for several reasons.

As a preliminary matter, should a court be unable to ascertain if it has jurisdiction, the court may remand under traditional principles to the agency for clarification, without reviewing the decision to issue an AWO. *See SEC v. Chenery Corp.*, 318 U.S. 80 (1943); *see also Zhu v. Ashcroft*, 382 F.3d 521 (5th Cir. 2004) (finding flawed analysis of merits of asylum claim and remanding for clarification of whether the BIA agreed with the immigration judge’s determination that the asylum application was untimely). If there have been new developments between the time of the immigration judge’s decision and the BIA’s AWO, and if the court is unable to determine the agency’s decision on a question reserved for appeal, the court also has authority under *Ventura* principles to remand for an agency decision, again, without resorting to independent review of the decision to issue an AWO. *See INS v. Ventura*, 537 U.S. 12, 16–18 (2002) (*per curiam*); *Haoud v. Ashcroft*, 350 F.3d 201, 208–09 (1st Cir. 2003) (remanding for an agency decision in

the first instance where there were intervening developments after the immigration judge’s decision not addressed by his decision). Additionally, when it is possible to conclude that one reviewable ground of the agency’s decision is valid and suffices as a basis for the immigration judge’s decision, the jurisdictional conundrum simply falls away. *See, e.g., Garcia-Melendez v. Ashcroft*, 351 F.3d 657, 661–62 (5th Cir. 2003) (finding that respondent applying for cancellation of removal had not established ten years’ continuous physical presence in the United States and denying the petition on that basis); *cf. Dia*, 353 F.3d at 272–73 (Stapleton, J., dissenting) (noting that the court may remand for further explanation if the court, upon examination of the record, is unable to sustain the decision on the grounds stated by the immigration judge and is unable to determine the agency’s reasoning on a particular point).

Commenters also objected that the Department’s intent regarding the nature and purpose of its regulations is immaterial to whether a court may independently review the BIA’s decision to issue an AWO. Settled case law, however, restricts judicial review of an agency’s compliance with procedural rules in instances in which the rule in question is designed primarily to benefit the agency carrying out its functions, rather than “to confer important procedural benefits upon individuals in the face of otherwise unfettered discretion.” *Am. Farm Lines v. Black Ball Freight Serv.*, 397 U.S. 532, 538–39 (1970). Agencies possess authority to create internal rules to govern their management and performance of their duties that are not intended to also create judicially enforceable rights. *See, e.g., Sandin v. Conner*, 515 U.S. 472, 481–83 (1995) (recognizing that regulations governing the adjudication of inmate disciplinary charges may be designed primarily to guide correctional officials in administering a prison, and not to create judicially enforceable rights in inmates). Under such circumstances, the agency’s compliance with its processes is traditionally not subject to review because the decision whether to follow those processes is committed to agency discretion by law. *See Heckler v. Chaney*, 470 U.S. 821, 826, 836 (1985) (FDA policy statement that agency is “obligated” to investigate unapproved uses of an approved drug when such use became “widespread” or “endanger[ed] the public health” did not create procedural right to insist on

investigation of state’s use of drugs in executing condemned prisoners).

The foregoing discussion and the relevant text in the final regulation seek to set forth the Department’s position as it has existed since the establishment of the streamlining process and to clarify that the rules governing § 1003.1(e)(4) through (6) are internal agency rules designed to assist the BIA in efficiently managing its caseload and carrying out its duties. The 2002 rule was successful in creating procedures that increased efficiency and promoted finality in immigration cases. The rule was not intended to create an additional layer of judicial review or a substantive right to review the form of the BIA’s decision. The efficient and fair adjudication of immigration appeals remains a priority of the Department. This revision to the regulations in no way reflects a diminished commitment to timely and fair adjudications at the administrative appeal level.

Accordingly, this final rule does not adopt the changes to 8 CFR 1003.1(e)(4) related to the AWO process in the proposed rule and retains the language noting that the decision to issue an AWO remains mandatory in appropriate circumstances. It also clarifies that a decision to issue any particular form of decision is a decision based on an internal agency rule or directive created for the purpose of efficient case management that does not create any substantive or procedural rights.

B. Scope of BIA’s Dispositions on Appeal

The 2008 proposed rule sought to provide regulatory authority for the Department’s longstanding position regarding the scope of a BIA decision regardless of the form of the decision. First, the proposed regulatory text provided that “[a] decision by the Board . . . carries the presumption that the Board properly and thoroughly considered all issues, arguments, claims and record evidence raised or presented by the parties, whether or not specifically mentioned in the decision.” 73 FR at 34663. The purpose of the proposed rule was to clarify that “the Board need not specifically address every issue raised on appeal, but is presumed to have considered all properly raised issues on appeal in reaching its decision, even if that decision is an AWO or short order that does not specifically discuss every issue the parties may have raised on appeal.” 73 FR at 34658 (citing, *e.g., Toussaint v. Att’y Gen.*, 455 F.3d 409 (3d Cir. 2006)).

Second, the rule proposed that the BIA’s decision, whether in the form of an AWO, a single-member decision, or

a three-member panel decision, is based on issues and claims of error that the parties raised on appeal and is not to be construed as waiving a party's obligation to exhaust issues and claims before the BIA. 73 FR at 34663. The proposed rule sought to clarify the parties' obligations to identify issues, arguments, and claims of error on appeal in a meaningful manner and with sufficient precision, even in instances where the BIA, in its discretion, *sua sponte* considers issues not raised on appeal. 73 FR at 34658. Third, the rule proposed to make clear that "the Board may address an issue that was not raised on appeal *sua sponte*." *Id.*

One commenter objected to the stated formalization of a presumption that the BIA properly and thoroughly adjudicates appeals before it, contending that the proposed rule would impede judicial review of BIA decisions and, in effect, would supersede the Department's commitment to provide a reasoned agency decision adequate for judicial review. The Department rejects this argument. The proposed presumption is simply a particularized statement of the well-settled presumption of regularity that attaches to agency processes. *See, e.g., INS v. Miranda*, 459 U.S. 14, 18 (1982) (presumption of regularity applied to agency adjudication of application for lawful permanent resident status). Board Members, like other government officials, "d[o] their jobs fairly, conscientiously and thoroughly." *Angov v. Lynch*, 788 F.3d 893, 905 (9th Cir. 2015) (applying the presumption of regularity to a Department of State letter reflecting the overseas investigation of an asylum claim). Moreover, the proposed rule does not supersede other regulations that govern BIA adjudications and is not intended to impede judicial review or supersede pertinent circuit precedent. *See* 8 CFR 1003.1; *Matter of Olivares-Martinez*, 23 I&N Dec. 148 (BIA 2001); *Matter of Anselmo*, 20 I&N Dec. 25 (BIA 1989).

With regard to exhaustion, the commenter objected to the proposed rule on the grounds that it is an improper attempt to regulate the jurisdiction of the courts of appeals and that use of the term "meaningful manner" creates a more demanding standard than the prevailing standards reflected in judicial opinions. In light of the comment, and upon further consideration, the Department believes that revisions are warranted to clarify the intent of the proposed rule.

As initially proposed in 2008, the rule provided that a BIA decision "is not to

be construed as waiving a party's obligation to exhaust administrative remedies by raising in a meaningful manner all issues and claims of error in the first instance on appeal to the Board." 73 FR at 34663. In adjudicating appeals, the BIA follows the party presentation rule. *See, e.g., Matter of M-A-S-*, 24 I&N Dec. 762, 767 n.2 (BIA 2009) (noting that DHS did not advance any argument on appeal about additional conditions on the immigration judge's voluntary departure order) (citing *Greenlaw v. United States*, 554 U.S. 237 (2008)). Under this rule, it is the responsibility of each party to advance its arguments on appeal to the BIA because adversarial proceedings "rely on the parties to frame the issues for decision and assign to [the adjudicator] the role of neutral arbiter of matters the parties present." *Greenlaw*, 554 U.S. at 243. This principle applies throughout "our adversary system, in both civil and criminal cases, in the first instance and on appeal." *Id.*; *see also Honcharov v. Barr*, No. 15-71554, 2019 U.S. App. LEXIS 15804, at *5-6 (9th Cir. May 29, 2019) (explaining that "[w]aiver and forfeiture are . . . important tools for preserving the structure of hierarchical court systems," and that these principles likewise "hold in the context of removal proceedings in the [EOIR]"). The proposed rule sought to reaffirm the obligation of the parties to raise any and all issues and claims before the BIA. *See* 8 CFR 1003.3(b), 1003.2(b); *see also* 8 CFR 1003.2(c) (requiring the parties moving to reopen proceedings to identify and specify findings and errors and state new facts to be proved). Indeed, when a party fails to specify the reasons for appeal, the BIA may summarily dismiss it without further consideration of the underlying merits of the case. 8 CFR 1003.1(d)(2)(i)(A). The requirement that the parties allege errors, issues, arguments, or claims with particularity aids the Board in adjudicating the cases before it. Thus, as is its practice, the BIA may decide an appeal or motion based on a party's failure to raise an alleged error, issue, argument, or claim before the BIA, the immigration court, or DHS immigration officer, if such error, issue, argument, or claim existed at the time of adjudication of the appealed matter. *See, e.g., Honcharov*, 2019 U.S. App. LEXIS 15804, at *6-7 (joining "every other circuit to have addressed the issue" in concluding that "the Board may apply a procedural default rule to arguments raised for the first time on appeal").

The Department seeks to clarify that the "obligation to exhaust," as set forth

in the proposed rule, is a separate and distinct matter from the doctrine of "exhaustion of administrative remedies," as set forth in section 242(d)(1) of the Immigration and Naturalization Act (the Act), which refers to the jurisdictional limits of a federal court's review of an issue.⁴ *See id.* at *5 n.2 (explaining that "[w]aiver and forfeiture in this context are related to, but distinct from, the doctrine[] of exhaustion"). Nonetheless, for purposes of clarification, the Department has removed the reference to exhaustion of administrative remedies in this final rule. The Department also has removed the "meaningful manner" language because it is not the Department's intention to establish a novel "meaningful manner" standard for presenting claims before the BIA. Instead, the rule seeks to simply reaffirm the need of the parties to raise any and all issues to the BIA on appeal. The rule further clarifies that the BIA, in the exercise of its discretion, may rule on an issue not raised by the parties on appeal if the issue was addressed in the underlying decision. However, this rule is not intended to alter the BIA's practice of not considering evidence proffered for the first time on appeal. *See, e.g., Matter of Soriano*, 19 I&N Dec. 764, 766 (BIA 1988). Finally, the Department has determined that, given the content of this aspect of the rule, this provision is more appropriately included in a new paragraph at § 1003.1(e)(9), rather than paragraph (e)(4), as previously proposed.

Accordingly, this final rule, in new § 1003.1(e)(9), states that a decision by the Board under paragraph (e)(4), (5), or (6) of that section carries the presumption that "the Board properly and thoroughly considered all issues, arguments, and claims raised or presented by the parties on appeal or in a motion that were deemed appropriate to the disposition of the appeal or motion, whether or not specifically mentioned in the decision." A decision also carries the presumption that the

⁴ Language in some decisions of the courts of appeals suggests that the BIA can waive the application of the exhaustion of remedies requirement set forth in section 242(d)(1) of the Act. However, that language, properly read, refers to the BIA's authority to consider an issue that was not presented, specified, or identified by the parties where the Board determines it is "administratively-ripe to warrant its appellate review," as distinguished from the separate question of whether an issue has been preserved for appellate review in the courts of appeals. *Sidabutar v. Gonzales*, 503 F.3d 1116, 1119-22 (10th Cir. 2007); *see also Bin Lin v. Att'y Gen.*, 543 F.3d 114, 122-26 (3d Cir. 2008); *Pasha v. Gonzales*, 433 F.3d 530, 532-33 (7th Cir. 2005); *Hassan v. Gonzales*, 403 F.3d 429, 432-33 (6th Cir. 2005); *Johnson v. Ashcroft*, 378 F.3d 164, 170 (2d Cir. 2004).

BIA did not need to consider any issue, argument, or claim not raised or presented by the parties on appeal or in the motion.

In addition to the issues discussed above, one commenter contended that the provision authorizing the BIA to consider issues *sua sponte* authorizes violations of the BIA's review standards and permits the BIA to engage in fact-finding in violation of regulatory or court rules. The commenter argued that allowing the BIA to consider issues *sua sponte* would "empower the BIA to provide the reasoning missing from an Immigration Judge's opinion so long as the issue was somehow presented before the Immigration Judge."

The commenter misunderstands the purpose of the rule. This rule is not intended to undermine the fact-finding authority or to supplement the fact-finding of the immigration judge. Rather, this rule is intended to allow the BIA to resolve issues, when necessary or appropriate, to ensure proper and thorough review of the appeal or motion before it, to provide guidance on the interpretation of the immigration laws and regulations, or to address recurring legal, procedural, and factual issues. Lastly, this provision permits the BIA to address the conduct of immigration judges when appropriate and where such issues were not raised by the parties.

Thus, the BIA must have the tools and flexibility to properly adjudicate the appeals and motions before it. The Department agrees with the commenter that there should be a vehicle by which parties, in appropriate cases, may be provided an opportunity to address dispositive issues the BIA wishes to consider *sua sponte* before the BIA renders a decision. For this reason, the final rule permits the BIA to set a supplementary briefing schedule where it chooses to consider an issue not raised by the parties in its discretion by stating, in § 1003.1(e)(9), that in any decision under paragraph (e)(5) or (6) of that section, "the Board may rule, in the exercise of its discretion as provided under this part, on any issue, argument, or claim not raised by the parties, and the Board may solicit supplemental briefing from the parties on the issue(s) to be considered before rendering a decision."

C. Three-Member Panel Decisions

The 2008 proposed rule sought to improve the BIA's review of complex and problematic cases by expanding the criteria for three-member decisions under 8 CFR 1003.1(e)(6). The public comments that addressed this provision

supported the decision to expand the criteria.

The proposed rule added a seventh criterion that would have allowed a BIA member, in the exercise of discretion, to refer a case to a three-member panel when the case presents a "complex, novel, or unusual issue of law or fact." See 73 FR at 34663. Upon further consideration, the Department is revising this criterion to state that a BIA member may refer a case for three-member review "to resolve a complex, novel, unusual, or recurring issue of law or fact." (Emphasis added.) Addition of the word "recurring" recognizes that the BIA is in the best position to identify issues that are recurring nationwide. Such issues may not result in inconsistent decisions among immigration judges or rise to the level of "major national import," see 8 CFR 1003.1(e)(6)(i), (iv), yet immigration judges, attorneys, respondents, and the federal courts still might benefit from guidance from the BIA on how to address such recurring issues. Allowing for referral to a three-member panel will result in enhanced review and analysis and perhaps publication of a precedent decision to provide nationwide guidance, if necessary.

Accordingly, the final rule adopts the proposal to expand the criteria to allow for referral to a three-member panel. This final rule amends 8 CFR 1003.1(e)(6) by adding a new paragraph (vii) to allow assignment to a three-member panel for review when there is a "need to resolve a complex, novel, unusual, or recurring issue of law or fact."

D. Publication of Precedent Decisions

One comment, which was endorsed by another commenter, expressed concern with the proposal to authorize a vote by three-member panels on whether to issue precedent decisions. The comment stated that the proposal is unnecessary, ripe for possible misuse, and lacking in adequate oversight and guarantees of uniformity. The comment stated that it would be a mistake to allow two permanent members of the BIA to issue a precedent decision without first obtaining approval of a majority of permanent BIA members. The comment reasoned that the proposed regulation allows only for notice to other members of the BIA; that there is nothing in the supplemental information to indicate that the existing system is burdensome or unworkable; and that the change will result in increased numbers of precedent decisions. The comment concluded that the BIA is currently issuing an adequate number of decisions and that the courts

are demonstrating appropriate deference to the BIA. In general, the Department agrees with these comments and has decided not to adopt the proposal to allow the BIA to issue precedent decisions by majority vote of permanent members of a three-member panel.

Although the number of BIA precedent decisions has varied from year to year, the Board has averaged nearly 29 precedent decisions each year over the last 14 years, and it has issued fewer than 23 precedent decisions only once, in 2005, when it issued 11. Consequently, it does not appear that the Board's current process for precedent decisions is unworkable or has inhibited it from providing necessary guidance through published decisions. In short, the Department has determined that the process currently in place for BIA's designation and publication of precedent decisions is appropriate and adequate.

Under this process, the BIA will continue to publish its precedent decisions as three-member panel decisions through the process of a majority vote of permanent members of the BIA and not, as initially proposed, by majority vote of the permanent BIA members assigned to a three-member panel. Adopting the proposed change would be counterproductive and inefficient, creating a greater likelihood of inconsistency among BIA member panels involving similar cases and issues that could be potentially selected for publication. Such potential for greater inconsistency and lack of uniformity among the panel decisions selected for publication would be further amplified by a recent regulation increasing the size of the BIA from 17 to 21 members. See *Expanding the Size of the Board of Immigration Appeals*, 83 FR 8321 (Feb. 27, 2018). Moreover, the mechanism for resolving this issue, considering a case *en banc*, does not substantively differ from the current procedure in which Board members vote *en banc* to publish a decision as precedent. Thus, the proposed change would simply add an additional level of process in order to ultimately achieve a similar result as the current process.

The BIA, as an appellate body and the highest administrative tribunal interpreting immigration law, is charged with, *inter alia*, providing clear and uniform guidance across the country in applying and interpreting immigration law. Ensuring that only the majority of permanent BIA members vote on and select cases to serve as precedent will continue to provide an invaluable safeguard against unnecessary and potentially conflicting outcomes in cases under the BIA's review. Moreover,

the participation of all BIA members in the precedent decision selection and voting process is essential to the efficient and collaborative function of the BIA. This final rule therefore does not adopt the proposal to allow the BIA to issue precedent decisions by majority vote of permanent members of three-member panels.

The Department did not receive any comments on the criteria for publication, in § 1003.1(g)(3)(i) through (vi) of the proposed rule, and adopts this provision with only one change. In addition to the standard in the proposed rule for a decision that “modifies or clarifies a rule of law or prior precedent,” the final rule also includes a reference to a decision that “distinguishes” a rule of law or prior precedent. This standard will allow the BIA to not only consider whether publication of a decision that “modifies, clarifies, or distinguishes” a rule of law or prior precedent is necessary to maintain consistency and uniformity, but also to consider whether a choice not to publish a decision that could potentially be seen as clarifying or distinguishing a prior precedent may result in a lack of clear guidance to immigration judges and parties as to the proper course to follow in other cases because an unpublished decision by the BIA is not binding in other cases.

As discussed above, the Attorney General expects that the BIA will continue to exercise its authority to issue precedent decisions as widely as is practicable to promote the consistency and uniformity of adjudications and to provide authoritative nationwide guidance to the immigration judges, the government, the respondents in immigration proceedings, petitioners for certain alien relatives, members of the immigration bar, and the federal courts with respect to the interpretation of ambiguous provisions of the immigration statutes and regulations and recurring legal, procedural, and factual issues arising in the adjudication of cases before the immigration judges, the U.S. Citizenship and Immigration Services, and the BIA.

E. Review of Decisions Involving Recognition and Accreditation

Although the regulations transferring responsibility for the recognition and accreditation program clarified the new designation of officials responsible for issuing decisions in those cases,⁵ the

prior regulatory changes did not address the precedential nature of any such decisions going forward, leaving EOIR without any specified authority to continue to issue precedent decisions to provide guidance in these cases. This oversight was unintentional, and EOIR continues to maintain that precedential guidance in recognition and accreditation cases is important, especially now that the BIA no longer issues the decisions in those cases. See 8 CFR 1292.18. The revisions to this part are matters relating to agency management or personnel and impose no burdens on the public. Further, although the Attorney General maintains plenary authority over immigration matters handled by EOIR, the transfer of oversight responsibility for the recognition and accreditation program from the BIA to OLAP did not include a specific mechanism for the referral of recognition and accreditation cases for review by the Attorney General.

For these reasons, the final rule corrects an oversight regarding precedent decisions involving EOIR’s recognition and accreditation program. This correction, which is a logical outgrowth of the broader review of the BIA’s use of precedent in the 2008 proposed rulemaking, allows for the continued publication of precedent decisions pertaining to recognition and accreditation, even though those decisions are no longer issued by the BIA. The final rule also corrects a related oversight by reestablishing an explicit mechanism for decisions involving recognition and accreditation to be referred to the Attorney General now that they are no longer adjudicated by the BIA.

IV. Regulatory Requirements

A. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act, the Attorney General certifies that this rule will not have a significant economic impact on a substantial number of small businesses or small governmental entities. This rule is related to agency organization and management of cases pending before the immigration judges and the Board. Accordingly, the preparation of a Regulatory Flexibility Analysis is not required.

reconsideration of any of these decisions. 8 CFR 1292.13, 1292.16, 1292.17. The EOIR Director adjudicates requests to review the reconsideration decisions of the OLAP Director. 8 CFR 1292.18.

B. Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

C. Congressional Review Act of 1996

This rule is not a major rule as defined by section 251 of the Congressional Review Act, 5 U.S.C. 804. This rule will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

D. Executive Orders 12866, 13563, and 13771 (Regulatory Review)

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of using the best available methods to quantify costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 13771 directs agencies to reduce regulation and control regulatory costs and, for all qualifying regulations, to identify at least two existing regulations for elimination.

This rule has been drafted in accordance with the principles of Executive Order 12866, section 1(b), and Executive Order 13563. Although the notice of proposed rulemaking in 2008 proposed changes to the AWO process, the final regulation does not adopt those changes and does not actually change any part of the AWO process nor amend the portions of 8 CFR 1003.1(e)(4) relating to AWOs. Consequently, there is no expected increase in the use of AWOs due to the final regulation.

Although the use of AWOs is not expected to increase as a result of the final regulation, the Department acknowledges that the final rule may nonetheless raise novel legal or policy issues. The Department thus considers

⁵ The OLAP Director adjudicates initial applications for recognition or accreditation, adjudicates requests for renewal of recognition or accreditation, and makes determinations on administrative termination of recognition or accreditation; he also adjudicates requests for

the rule to be a “significant regulatory action” under section 3(f)(4) of Executive Order 12866, and the regulation has accordingly been submitted to the Office of Management and Budget for review.

Finally, this rule is exempt from the requirements of Executive Order 13771 because this rule concerns regulations related to agency organization, management, or personnel. The final rule is an internal rule of procedure that relates to the management of immigration cases on appeal. It does not alter any substantive rights, and it conforms to existing directives on the efficient management and disposition of cases. Accordingly, it does not impose any additional costs on the processing of cases on appeal.

E. Executive Order 13132 (Federalism)

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, this rule does not have sufficient federalism implications to warrant preparation of a federalism summary impact statement.

F. Executive Order 12988 (Civil Justice Reform)

This rule has been prepared in accordance with the standards in sections 3(a) and 3(b)(2) of Executive Order 12988.

G. Paperwork Reduction Act

This rule is exempt from the requirements of the Paperwork Reduction Act because it does not create any information collection requirements.

List of Subjects

8 CFR Part 1003

Administrative practice and procedure, Aliens, Immigration, Legal services, Organization and functions (Government agencies).

8 CFR Part 1292

Administrative practice and procedure, Immigration, Lawyers, Referrals, Precedent decisions.

Accordingly, for the reasons set forth in the preamble, 8 CFR parts 1003 and 1292 are amended as follows:

PART 1003—EXECUTIVE OFFICE FOR IMMIGRATION REVIEW

■ 1. The authority citation for part 1003 continues to read as follows:

Authority: 5 U.S.C. 301; 6 U.S.C. 521; 8 U.S.C. 1101, 1103, 1154, 1155, 1158, 1182, 1226, 1229, 1229a, 1229b, 1229c, 1231, 1254a, 1255, 1324d, 1330, 1361, 1362; 28 U.S.C. 509, 510, 1746; sec. 2 Reorg. Plan No. 2 of 1950; 3 CFR, 1949–1953 Comp., p. 1002; section 203 of Pub. L. 105–100, 111 Stat. 2196–200; sections 1506 and 1510 of Pub. L. 106–386, 114 Stat. 1527–29, 1531–32; section 1505 of Pub. L. 106–554, 114 Stat. 2763A–326 to –328.

■ 2. Section 1003.1 is amended:

■ a. In paragraph (e)(6)(iii), by removing “the Service” and adding in its place “DHS”;

■ b. In paragraph (e)(6)(v), by removing “or”;

■ c. In paragraph (e)(6)(vi), by removing “the Service” and adding in its place “DHS” and by removing the period at the end and adding in its place “; or”;

■ d. By adding paragraphs (e)(6)(vii) and (e)(9); and

■ e. By revising paragraph (g).

The additions and revision read as follows:

§ 1003.1 Organization, jurisdiction, and powers of the Board of Immigration Appeals.

* * * * *

(e) * * *

(6) * * *

(vii) The need to resolve a complex, novel, unusual, or recurring issue of law or fact.

* * * * *

(9) The provisions of paragraphs (e)(4)(i) and (e)(5) and (6) of this section are internal agency directives for the purpose of efficient management and disposition of cases pending before the Board and are not intended to create any substantive or procedural rights to a particular form of Board decision. A decision by the Board under paragraph (e)(4), (5), or (6) of this section carries the presumption that the Board properly and thoroughly considered all issues, arguments, and claims raised or presented by the parties on appeal or in a motion that were deemed appropriate to the disposition of the appeal or motion, whether or not specifically mentioned in the decision. A decision by the Board under paragraph (e)(4), (5), or (6) also carries the presumption that the Board did not need to consider any issue, argument, or claim not raised or presented by the parties on appeal or in a motion to the Board. In any decision under paragraph (e)(5) or (6) of this section, the Board may rule, in the exercise of its discretion as provided under this part, on any issue, argument, or claim not raised by the parties, and the Board may solicit supplemental briefing from the parties on the issues to

be considered before rendering a decision.

* * * * *

(g) *Decisions as precedents*—(1) *In general.* Except as Board decisions may be modified or overruled by the Board or the Attorney General, decisions of the Board and decisions of the Attorney General are binding on all officers and employees of DHS or immigration judges in the administration of the immigration laws of the United States.

(2) *Precedent decisions.* Selected decisions designated by the Board, decisions of the Attorney General, and decisions of the Secretary of Homeland Security as provided in paragraph (h)(2)(i) of this section will be published and serve as precedents in all proceedings involving the same issue or issues.

(3) *Designation of precedents.* By majority vote of the permanent Board members, or as directed by the Attorney General or his designee, selected decisions of the Board issued by a three-member panel or by the Board *en banc* may be designated to be published and to serve as precedents in all proceedings involving the same issue or issues. In determining whether to publish a precedent decision, the Board may take into account relevant considerations, in the exercise of discretion, including among other matters:

(i) Whether the case involves a substantial issue of first impression;

(ii) Whether the case involves a legal, factual, procedural, or discretionary issue that can be expected to arise frequently in immigration cases;

(iii) Whether the issuance of a precedent decision is needed because the decision announces a new rule of law, or modifies, clarifies, or distinguishes a rule of law or prior precedent;

(iv) Whether the case involves a conflict in decisions by immigration judges, the Board, or the federal courts;

(v) Whether there is a need to achieve, maintain, or restore national uniformity of interpretation of issues under the immigration laws or regulations; and

(vi) Whether the case warrants publication in light of other factors that give it general public interest.

* * * * *

PART 1292—REPRESENTATION AND APPEARANCES

■ 3. The authority citation for part 1292 continues to read as follows:

Authority: 8 U.S.C. 1103, 1362.

■ 4. In § 1292.18, add paragraphs (c) and (d) to read as follows:

§ 1292.18 Administrative review of denied requests for reconsideration.

* * * * *

(c) *Referral of cases to the Attorney General.* The Director will refer to the Attorney General for review of decisions pursuant to this section in all cases that the Attorney General directs the Director to refer to him or that the Director believes should be referred to him.

(d) *Decisions as precedents.* The Director, in his discretion, may cause reconsideration decisions by the OLAP Director pursuant to § 1292.13(e), § 1292.16(f), or § 1292.17(d), or decisions by the Director pursuant to this section to be published as precedents in the same manner as decisions of the Board and the Attorney General. Such decisions by the OLAP Director, except as overruled by the Director, and such decisions by the Director, except as overruled by the Attorney General, will serve as precedents in all proceedings under part 1292 involving the same issue or issues.

Dated: June 25, 2019.

William P. Barr,
Attorney General.

[FR Doc. 2019–13933 Filed 7–1–19; 8:45 am]

BILLING CODE 4410–30–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 10 and 800

[Docket No. FDA–2016–N–2378]

RIN 0910–AH37

Internal Agency Review of Decisions; Requests for Supervisory Review of Certain Decisions Made by the Center for Devices and Radiological Health

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing a final rule to amend its regulations regarding internal agency supervisory review of certain decisions related to devices regulated by the Center for Devices and Radiological Health (CDRH or the Center) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to conform to the applicable provisions in the FD&C Act, as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA) and the 21st Century Cures Act (Cures Act). This final rule codifies the

procedures and timeframes for supervisory review of significant decisions pertaining to devices within CDRH. FDA is also finalizing regulations to provide new procedural requirements for requesting internal agency supervisory review within CDRH of other types of decisions made by CDRH not addressed in FDASIA and the Cures Act. This action is also part of FDA's implementation of Executive Orders (EOs) 13771 and 13777. Under these EOs, FDA is comprehensively reviewing existing regulations to identify opportunities for repeal, replacement, or modification that will result in meaningful burden reduction, while allowing the Agency to achieve its public health mission and fulfill statutory obligations.

DATES: This rule is effective August 1, 2019.

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this final rule into the “Search” box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

With regard to the final rule: Adaeze Teme, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5574, Silver Spring, MD 20993–0002, 240–402–0768; or the Ombudsman for the Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4282, Silver Spring, MD 20993–0002, 301–796–5669, or CDRHombudsman@fda.hhs.gov.

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I. Executive Summary

A. Purpose of the Final Rule

FDA is issuing this final rule to implement regulations on the procedures regarding internal agency supervisory review of certain decisions made by CDRH under the FD&C Act. Section 603 of FDASIA (Pub. L. 112–144) added new section 517A to the FD&C Act (21 U.S.C. 360g–1), which was amended by sections 3051 and 3058 of the Cures Act (Pub. L. 114–255). These provisions established procedures and timeframes for supervisory review under Title 21 of the Code of Federal Regulations (CFR) § 10.75 (21 CFR 10.75) of significant decisions by CDRH pertaining to devices. After the enactment of FDASIA, FDA issued a guidance document entitled “Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A—Guidance for Industry and Food and Drug Administration Staff” (Q&A Guidance) to provide interpretation of key provisions of section 517A of the FD&C Act, including those that pertain to requests for supervisory review of significant decisions by CDRH (available at: <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM352254.pdf>). FDA is finalizing this regulation to codify: (1) The procedures and timeframes for § 10.75 appeals of “significant decisions” by CDRH established under section 517A and (2) the interpretation of key provisions of section 517A of the FD&C Act regarding supervisory review. In addition, the regulations codify new procedural requirements for supervisory review within CDRH of other CDRH decisions that were not addressed in FDASIA and the Cures Act.

The final rule provides transparency and clarity for internal and external stakeholders on CDRH's process for supervisory review of decisions and provides requesters new predictability through binding deadlines for FDA action on a request for supervisory review within CDRH and the Center's internal agency review of “significant decisions.” Furthermore, this final rule codifies the types of decisions that are considered “significant decisions,” for which the timeframes apply. The final regulations also codify the timeframe for submission of requests for the review of other decisions within CDRH.