



The General
Counsel
Washington, D.C.
20201

MEMORANDUM

TO: Operating Division Heads and Office Directors

FROM: Alex M. Azar II, Secretary

SUBJECT: Fairness in Administrative Enforcement and Adjudication

DATE: January 12, 2021

Fairness and transparency foster public trust in administrative procedures and functions. The U.S. Department of Health and Human Services (“HHS” or “the Department”) is committed to acting transparently and fairly with respect to all regulated persons, including parties in administrative enforcement and adjudication proceedings. Because administrative agencies, such as HHS, institute civil enforcement actions, and can impose substantial fines, penalties, and other burdens on regulated persons, it is especially important that the public have confidence that these actions are conducted in a fair and transparent manner that appropriately balances the needs to ascertain the truth, punish regulatory violations, and not impose undue burdens on regulated persons.

To implement these goals, as well as Section 6 of Executive Order 13924 of May 19, 2020, “Regulatory Relief to Support Economic Recovery,” 85 Fed. Reg. 31,353 (May 22, 2020) (“Section 6”), I hereby direct the heads of the Department’s operating divisions and offices to review and revise their procedures related to civil enforcement actions and adjudications to ensure that they promote fairness and transparency. When reviewing and revising their procedures, divisions and offices shall give strong consideration to implementing the following, to the extent they have not yet done so.¹

I. Burden of Proof Rests with the Department.

- (a) In all civil enforcement actions,² unless contrary to applicable law, the Department adjudicator³ should impose upon the Department the burden of proving an alleged violation of law, consistent with *Director, Office of Workers’ Compensation Programs, Dep’t of Labor v. Greenwich Collieries*, 512 U.S. 267 (1994).
- (b) In all civil enforcement actions, unless contrary to applicable law, the Department adjudicator should not impose upon the subject of enforcement the burden of proving compliance with law.

¹ These measures are consistent with the best practices that the Office of Management and Budget described in its *M-20-31 Memorandum for the Deputy Secretaries of Executive Departments and Agencies*, Aug. 31, 2020.

² “Civil enforcement action” has the meaning ascribed to it in 45 C.F.R. § 1.2, except that this memo does not apply to any action taken by the Office of Inspector General or Office of Inspector General audits (including audit findings and audit recommendations).

³ “Department adjudicator” means a line adjudicator of a civil enforcement action, administrative appellate reviewer of a civil enforcement action, and those engaging in informal adjudications of civil enforcement actions.

Unless contrary to law, the Department adjudicator should not require the subject of enforcement to prove a negative to prevent liability and enforcement consequences.

- (c) Department adjudicators should apply the rule of lenity in civil enforcement actions where a genuine statutory or regulatory ambiguity is at issue. Department adjudicators shall read genuine statutory or regulatory ambiguities (as understood in *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019)) related to administrative or regulatory violations and penalties in favor of the subject of enforcement.

II. Fairness in Civil Enforcement Actions.

Civil enforcement actions should be prompt and fair. This directive shall not affect current Department practices with respect to working with regulated entities to cure alleged violations of law without resort to a civil enforcement action.

- (a) Before entering into a tolling agreement that would have the effect of extending the statute of limitations for a violation, the Department should generally seek approval of an Officer of the United States (*see* U.S. Const. art. II, §2, cl. 2), or, if necessitated by good cause, by or his or her designee.
- (b) If a party has been informed by the Department that it is under investigation, the Department should inform the party when the investigation is closed and, when the Department has made no finding of violation, so state.
- (c) Department adjudicators shall consider and appropriately apply estoppel and res judicata principles to eliminate multiple enforcement actions for a single body of operative facts.
- (d) The performance metrics and compensation structures for Department employees should incentivize excellence, accuracy, integrity, efficiency, and fairness in the application and execution of the law. Performance metrics should not detract from the aim of reaching fact-based, unbiased decisions with respect to all aspects of enforcement. Department employees should not be rewarded on any basis that incentivizes them to bring cases or seek penalties or settlements that are meritless, unwarranted, or disproportionate.
- (e) Retaliatory or punitive motives, or the desire to compel capitulation, should not form the Department's selection of targets for investigations or civil enforcement actions, or other investigation and civil enforcement decisions.
- (f) Fines, penalties, or settlement funds arising from a civil enforcement action should not be used to supplement the budget of the Department component that brought the civil enforcement action in a way that would incentivize bringing civil enforcement actions that are meritless or unwarranted.

III. Independence of Department Adjudicators.

Department adjudicators should operate independently of enforcement staff on matters on which the Department adjudicators are adjudicating.

- (a) Department adjudicators should not engage in ex parte communications with, and should operate independently from, investigators and enforcement staff, as the Administrative Procedure Act requires for formal adjudications under 5 U.S.C. §§ 554(d) and 557(d), even if the civil enforcement action is not subject to 5 U.S.C. §§ 554(d) or 557(d).
- (b) Line adjudicators should not engage in ex parte communications with, and should operate independently from, administrative appellate adjudicators on matters on which they are adjudicating.
- (c) Department adjudicators' performance metrics and compensation structures should incentivize fact-based, unbiased adjudication decisions. Department adjudicators should not be rewarded based on the penalties they award, finding in favor of any particular party, or in any other way that would create the appearance of bias.

IV. Applicability of the Rules of Evidence and Procedure to Civil Enforcement Actions.

All rules of evidence and procedure should be public, clear, and effective.

- (a) Unless contrary to statute or legislative regulation, Department adjudicators should seek to apply the Federal Rules of Evidence and relevant parts of the Federal Rules of Civil Procedure in civil enforcement actions. Where a regulation governing the civil enforcement action provides that the Department adjudicator can, but need not, apply the Federal Rules of Evidence, the Department adjudicator should supply a reasoned explanation if he or she decides not to apply the Federal Rules of Evidence.
- (b) Department adjudicators should apply the framework in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999) with respect to expert scientific and technical evidence presented or sought to be presented in a civil enforcement action.
- (c) Consistent with any Executive Branch confidentiality interests, in civil enforcement actions, the Department should disclose exculpatory evidence and evidence material to the mitigation of damages, fines, or penalties to the subject of enforcement in a manner consistent with what would be required under *Brady v. Maryland*, 373 U.S. 83, 87 (1963), *Giglio v. United States*, 405 U.S. 150, 154 (1972), and *Kyles v. Whitley*, 514 U.S. 419, 432-33 (1995) if the civil enforcement action were a criminal case. The Department need not disclose such evidence if it is certain that the subject of enforcement already possesses the evidence. Under this paragraph,
 - i. Agency officials should timely disclose exculpatory evidence to the subject of enforcement using similar procedures as those laid out in the *Justice Manual* of the U.S. Department of Justice (previously known as the *U.S. Attorney's Manual*).
 - ii. These affirmative disclosures should include any material evidence known to the Department's enforcement personnel that may be favorable to the subject of the civil enforcement action—including evidence that tends to negate or diminish the party's responsibility for a violation or that could be relied upon to reduce the potential damages, fines, or other penalties.
- (d) In keeping with the requirements contained in 5 U.S.C. § 555(b), subjects of civil enforcement actions can, unless prohibited by applicable law, be represented by legal counsel and, in appropriate cases, by qualified representatives as that term is used in 5 U.S.C. § 555(b).

V. Standards for Imposing Penalties.

Civil penalties should be proportionate, transparent, and imposed in adherence to consistent standards and only as authorized by law.

- (a) The Department should in many cases decline enforcement or the imposition of a penalty or fine, as appropriate, in the course of a civil enforcement action when the agency determines that the subject of enforcement attempted in good faith to comply with the law. There may be times where it is appropriate to impose a penalty or fine on a subject of enforcement that attempts in good faith to comply with the law. Examples where this is the case might include where the penalty or fine is imposed pursuant to a statute or regulation that clearly specifies a violation can occur even if the subject of enforcement attempted in good faith to comply with the law. However, in many cases, the Department's limited resources will be better used to impose penalties or fines on bad-faith actors, rather than those who attempted in good faith to comply with the law.
- (b) Unless otherwise prescribed by statute, the Department should endeavor to include expiration dates or termination criteria in consent orders, consent decrees, and settlement agreements that are proportionate to the violation of the law that is being remedied.
- (c) Consent orders, consent decrees, and settlement agreements should not bar subjects of enforcement from disseminating information about their cases that is not otherwise prohibited from disclosure.

VI. Accountability for Civil Enforcement Actions.

- (a) For civil enforcement actions initiated after the implementation of these procedures, approval of an Officer of the United States or, if necessitated by good cause, his or her designee, is required prior to the initiation of any civil enforcement action. The approving Officer or designee shall condition approval upon the Department complying with these procedures, as they pertain to the civil enforcement action.
- (b) Each operating division within the Department shall identify, collect, and periodically make publicly available decisional quality and efficiency metrics regarding administrative adjudications under bureaucratic, judicial, and split enforcement models of adjudication. These metrics shall include the number of matters that have been pending with the Department over relevant time periods, the number of matters disposed of by the Department annually, and data on the types of matters before and disposed of by the Department. This paragraph shall not require the disclosure of any information protected by any legal privilege or confidentiality interest.

Alex M. Azar II

Date