

THE JOURNAL OF FEDERAL AGENCY ACTION

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Department of Health and Human Services Office of General Counsel Statement of Organization Suggests Potential Consolidation, Expansion of Authority

Jaime L.M. Jones, Meenakshi Datta, Rebecca K. Wood, Raj D. Pai, Colleen Theresa Brown, and Michael Varrone*

In this article, the authors review the revised Statement of Organization issued recently by the Department of Health and Human Services for its Office of the General Counsel.

The Department of Health and Human Services (HHS) has issued a revised Statement of Organization¹ for the Office of the General Counsel (HHS-OGC).² Changes include a return to an organizational structure more like the early days of the first Trump administration for the lawyers advising the Food and Drug Administration (FDA), as well as the closing of certain regional HHS-OGC offices. Additional changes could potentially signal an effort to consolidate and expand HHS-OGC's authority, especially with respect to matters currently opined upon by lawyers advising the HHS Office of Inspector General (HHS-OIG). Stakeholders should consider opportunities to engage with HHS in light of the changes announced in the Statement of Organization.

Certain changes to HHS-OGC's organization were recently pre-viewed by HHS-OGC in a website posting.³ With respect to FDA, in the latter part of the first Trump administration, HHS-OGC merged the roles of the FDA Chief Counsel and the HHS Deputy General Counsel for Food and Drugs. The most recently announced changes return to the separate positions structure from the early part of the first Trump administration and give additional responsibility to the Deputy General Counsel. The Deputy General Counsel is now known as the "Deputy General Counsel/Chief Counsel for Food,

Research, and Drugs” and oversees the Food and Drug Division of HHS-OGC (known as FDA’s “Office of the Chief Counsel” at FDA) as well as the National Institutes of Health Branch of OGC. The FDA Chief Counsel (also known as the “Associate General Counsel, Food and Drug Division,” as it was in the early part of the first Trump administration) will report to the Deputy General Counsel/Chief Counsel for Food, Research, and Drugs.

In addition, HHS-OGC is closing six of its ten regional offices, a move characterized as a consolidation effort to “lower operating costs.”⁴ HHS-OGC regional offices have had a broad range of responsibilities, often involving surveys/inspections of providers and enforcement actions relating to privacy and civil rights laws. In the near term, the closures may result in delays for matters handled by regional offices and a bigger role for the main office of HHS-OGC.

Notable Changes

The Statement of Organization also makes several other notable changes:

- *“Binding” Legal Advice.* HHS-OGC’s “Mission” statement has been updated to state that HHS-OGC’s legal advice “shall be binding on the Department unless overturned by the Secretary.” Historically, HHS-OGC’s legal advice was not uniformly viewed as binding by policymaking components of HHS.
- *Relationship Between HHS-OGC and the Office of Counsel to the Inspector General (OCIG).* HHS-OIG has its own legal department, OCIG, that sits outside of the HHS-OGC organizational structure and has no political appointees. OCIG advises HHS-OIG on all of its work, ranging from traditional Inspector General responsibilities as set out in the Inspector General Act of 1978 to work HHS has delegated to HHS-OIG, such as interpretation and enforcement of the Anti-Kickback Statute. Prior iterations of the HHS-OGC Statement of Organization acknowledged that HHS-OIG “is authorized to have its own Office of the Counsel to the Inspector General.” However, the Statement of Organization says that HHS-OIG is authorized to have

its own counsel “with respect to matters solely within the OIG’s jurisdiction.”

Similarly, the HHS-OGC description of responsibilities previously stated that HHS-OGC “[s]upervises all legal activities of the Department and its operating and staff divisions, except the OIG.” That language has been updated to say “except with respect to certain matters within the jurisdiction of the OIG.” HHS-OGC may begin taking the position that certain legal issues OCIG currently advises on are not “solely within” HHS-OIG’s jurisdiction and thus are the province of HHS-OGC, not OCIG. For example, the Inspector General Act of 1978 requires each federal agency to establish an Office of Inspector General but prohibits agencies from “transferr[ing] to such office any program operating responsibilities.”⁵ HHS-OGC may take the position that certain areas on which OCIG currently opines, including potentially areas involving enforcement of the Anti-Kickback Statute, implicate program operating responsibilities and cannot by law be within the sole jurisdiction of HHS-OIG or OCIG. Healthcare companies faced with HHS-OIG enforcement actions may wish to consider whether HHS-OGC’s newly articulated position should inform their defense strategies.

- *HHS-OGC Now Conducts Internal Investigations.* The Statement of Organization indicates that the National Complex Litigation and Investigation Division—a new division HHS-OGC created during the first Trump administration to handle a rising tide of complex litigation—will “conduct internal investigations at the request of the Secretary, Deputy Secretary, or General Counsel.” The scope and subject matter of such internal investigations is not clear. HHS-OGC has not historically conducted internal investigations, which would generally be performed by HHS-OIG.
- *New “Civil Rights and Health, Privacy, and Technology Division.”* HHS-OGC moved the legal team advising the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP/ONC) outside of the Centers for Medicare & Medicaid Services (CMS) Division and into the Civil Rights and Health Division (CRD), which is now called the Civil

Rights and Health, Privacy, and Technology Division. This new division comprises two branches, the Civil Rights Branch and the Health Information Privacy and Technology Branch, each of which is headed by a Deputy Associate General Counsel. Responsibilities include “providing legal advice on all civil rights, health policy, privacy, and related policy and enforcement matters in the Department, with the exception of defending claims filed by employees of HHS.” CRD already had responsibility for Health Insurance Portability and Accountability Act enforcement, and this move consolidates privacy and technology-related work within HHS-OGC at a time of rapid digital transformation in the health sector, including from artificial intelligence innovation.

- *Changes to Remaining Regional Office Caseload.* The Statement of Organization removes the following CRD-related work from the responsibilities of the now-four regional offices: “providing legal services to the Office for Civil Rights, including advice and representation in administrative and judicial litigation with respect to the enforcement of civil rights laws and the Health Insurance and Portability and Accountability Act of 1996.” The priorities of the HHS Office for Civil Rights often swing dramatically between changes in administration, and this move may be designed to ensure sufficient political oversight over civil rights matters.
- *Potentially Greater HHS-OGC Involvement in FDA-Related Enforcement Actions.* FDA’s Office of Chief Counsel (also known as the Food and Drug Division of HHS-OGC (FDD)) advises the Commissioner of Food and Drugs and provides legal services to FDA and HHS officials on matters involving FDA-regulated products. FDD refers civil and criminal enforcement cases to the Department of Justice (DOJ), and it works closely with DOJ on those enforcement matters and on defending challenges to provisions of the Federal Food, Drug, and Cosmetic Act (FDCA), the implementing regulations, and FDA policies, initiatives, and decisions. Although the Deputy General Counsel and General Counsel of HHS typically are not involved in OCC/FDD’s referrals of enforcement matters to DOJ, this administration has signaled that they may take a more

active role. The Statement of Organization explains that “all criminal prosecutions, investigations, and civil matters may be referred to the Department of Justice only through or in consultation with the Chief Counsel, appropriate Deputy General Counsel or the General Counsel.”

- *HHS-OGC Advisory Opinion Authority.* During the first Trump administration, HHS-OGC began issuing ad hoc advisory opinions announcing its position on legal issues. HHS posted the advisory opinions to the HHS Guidance Portal.⁶ HHS-OGC under the Biden administration continued this practice. The Statement of Organization memorializes as an HHS-OGC responsibility “[i]ssu[ing] all Advisory Opinions except those relating to the Anti-Kickback Act (SSA 1128B(b)), the Anti-Inducement Act (SSA 1128A(a)(5)), and the Ethics in Patient Referral Act of 1989,” that is, the Stark Law. HHS-OIG issues advisory opinions relating to the Anti-Kickback Act and Anti-Inducement Act, and CMS issues advisory opinions relating to the Stark Law. Stakeholders can expect to continue to see HHS-OGC issue advisory opinions on other topics and may consider opportunities to engage with HHS-OGC on appropriate subjects for advisory opinions.

Notes

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1. <https://www.federalregister.gov/documents/2025/03/14/2025-04130/statement-of-organization-functions-and-delegations-of-authority>.

2. 90 Fed. Reg. 12,166 (Mar. 14, 2025).

3. <https://www.hhs.gov/about/news/ogc-reorganization-effort.html>.

4. *Id.*

5. 5 U.S.C. § 415(b).

6. <https://www.hhs.gov/guidance/>.