Getting to Know Government Attorneys:
A Look at CDC and CMS
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Moderator

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The Government Attorneys Interest Group (GAIG) provides networking and engagement opportunities, programs, publications, and online resources for lawyers whose practice or interests lie at the intersection of government and healthcare.

Membership is composed of Health Law Section members who have an interest in or experience working with or for governmental healthcare entities on the federal, state, tribal, local, or territorial jurisdictional level.

The IG serves as a resource for these attorneys by providing a mechanism for sharing best practices, recent trends, proposed and new regulations and agency mandates, documents, policies, protocols and forms, implementation of laws and regulations, and content expertise.

https://www.americanbar.org/groups/health_law/interest_groups/networking_engagement/Govt/
Two quick points

Recording

• Today’s session will be recorded.
  – available within 24hrs
  – ABA Interest Group’s website.
  – Go to: ambar.org/health
    • Click “ Networking & Engagement Interest Groups”
    • Click “Government Attorneys”

Q/A

• Type your questions into the “Question Box” on your control panel, either during or after the presentation.
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Getting to Know Government Attorneys: CDC

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Disclaimer: View expressed are those of the presenter and do not necessarily represent the policy positions of HHS or CDC.

Heather Huntley, JD, MHA
Office of the General Counsel
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Roles of the OGC

- Legal advice
- Interpret statutory and regulatory authority
- Assist in rulemaking dockets and federal register notices
- Review documents for legal sufficiency
  - Program announcements
  - Letters
  - MOUs/MOAs
  - Policy statements
- Contact point for government and private attorneys
  - Civil and criminal DOJ litigation
Examples of Laws and Legal Issues Relevant to CDC

Copyright
Privacy Act
Health Insurance Portability and Accountability Act (HIPAA)
Freedom of Information Act (FOIA)
Lobbying
Testimony Regulations
Federal Tort Claims Act (FTCA)
Copyright

Copyright is a form of protection provided by federal law for original works of authorship for the purpose of promoting artistic and cultural creativity.

- Applies to literary works, including books, magazines, journals and newspapers, as well as photographs, videos, artistic and other intellectual work.
Fair Use Exception

• Federal copyright law permits the “fair use” of copyrighted material.

• Fair use = use of copyrighted material without the copyright owner’s permission for certain purposes such as teaching, scholarship, and research.

  – Many Government uses of copyrighted materials for internal purposes are “fair”; however, the Government is subject to copyright infringement.

  – Copyright protection is not available for works prepared by officers or employees of the U.S. Government as part of that person’s official duties.
Privacy Act

Intended to increase citizens’ access to information and enhance governmental transparency.

- Protects an individual’s privacy.
- Provides an individual access to that individual’s own information.
- Provides requirements for notification upon request.
Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule

- HIPAA Privacy Rule
  - Provides protection for the privacy of certain “protected health information.”
  - Permits disclosures without individual authorization to public health authorities authorized by law to receive such information to perform public health activities.
  - CDC is a public health authority, *not* a covered entity for most purposes.
Freedom of Information Act (FOIA)

- Permits access to all records kept by CDC unless an exemption applies.
- “Records” includes drafts, phone messages, marginal notes.
- Records must be in control of CDC at time of request.
Anti-Lobbying Act

- Federal law (18 U.S.C. 1913) prohibits the direct or indirect use of appropriated funds for any communication intended to influence a “Member of Congress, a jurisdiction, or an official of any government . . .” in acting on “any legislation, law, ratification, policy, or appropriation . . . before or after [its] introduction.”
Testimony by CDC Employees in Private Litigation

• Generally, current and former CDC employees do not participate as witnesses in private litigation.

• Supports policy of:
  • Maintaining impartiality in disputes, and
  • Minimizing disruption of official duties.

But, there are exceptions . . .
The State of Texas v. Kimberly Clark Saenz
• In 2008, CDC was asked by Texas health officials to investigate a dialysis facility where an increased number of ambulance transports for adverse events were occurring in patients receiving hemodialysis at the facility.

• What began as a standard public health investigation led to a criminal investigation when patients in the facility reported observing Kimberly Saenz inject chlorine bleach into the intravenous lines of other dialysis patients.

• CDC epidemiologists, toxicologists, and dialysis experts connected Saenz to patients who had adverse health events.
• The State of Texas charged Saenz with one count of capital murder and five counts of aggravated assault with a deadly weapon – bleach.

• CDC employees were permitted to assist pursuant to HHS regulations (45 CFR Part 2) governing testimony by CDC employees in cases where the U.S. Government is not a party.

• CDC assisted the prosecution by supplying and interpreting documents related to the public health investigation of the dialysis center and educating the Texas prosecutor about epidemiology and CDC’s public health role in the investigation.
• At the criminal trial, CDC employees provided key testimony related to dialysis and the toxicology of bleach.

• On March 30, 2012, the jury found Saenz guilty on one count of capital murder for killing at least two people by injecting them with bleach, and on three counts of aggravated assault.
Federal Tort Claims Act (FTCA)

• A waiver of sovereign immunity.

• If sued, an employee must request representation from DOJ.

• Does NOT apply to—
  • Incidents outside of the U.S.
  • Reckless, willful, or criminal conduct
FTCA Case
Salmonella Saintpaul outbreak
• CDC helped defend against a food safety-related lawsuit brought against CDC and FDA in *Seaside Farm v. United States*.

• Plaintiff filed a civil action seeking more than $15 million in damages it allegedly sustained after FDA and CDC warned the public in June 2008 that certain tomatoes were contaminated with Salmonella Saintpaul.

• Plaintiff alleged that it was unable to sell its tomato crop and that its business reputation was damaged because of CDC and FDA’s negligence in implicating tomatoes in the outbreak.
The FTCA’s Discretionary Function Exception

- No liability for “the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government ..." (28 U.S.C. § 2680(a)).

- Intended scope of this exception not entirely clear; no sharp well-defined test for the application of this exception.
The FTCA’s Discretionary Function Exception

- The *most sweeping* of the FTCA exceptions
- Bars claims arising not only from high-level planning decisions or agency regulations, but also from routine, low-level actions
  - A postal official’s decision where to place a mailbox
  - A Forest Service ranger’s decisions about how to maintain a campsite
  - A mass transit official’s decisions about when and how station floors should be mopped
The FTCA’s Discretionary Function Exception

The District court held that the FDA was exercising a discretionary function in connection with the contamination warning. The 4th Circuit affirmed.
QUESTIONS?

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The Center for Medicare & Medicaid Innovation (CMMI)

Medicare-Medicaid Coordination Office (MMCO)

Disclaimer: This presentation and the views expressed are those of the presenter and do not represent the policy positions of CMMI or MMCO
CMMI was established by section 1115A of the Social Security Act (as added by Section 3021 of the Affordable Care Act in 2010)

Created for purpose of developing and testing innovative health care payment and service delivery models within Medicare, Medicaid, and CHIP programs nationwide

CMMI has a growing portfolio testing various payment and service delivery models that aim to achieve better care for patients, better health for our communities, and lower costs through improvement for our health care system

CMMI plays a critical role in implementing the Quality Payment Program, which Congress created as part of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

Episode-based Payment Initiatives
Roles in CMMI and Model Development

- Construct regulations and guidance on national health insurance programs
- Contribute to the development and design of current and forthcoming CMMI models
- Draft beneficiary notifications, privacy documents, and internal and external guidance documents related to issues such as, healthcare fraud and abuse, personally identifiable information, data sharing, payment policy waivers, and model compliance
- Prepare Congressional documents, reports, summaries, responses to requests for information and other substantive documents
CJR Model tests bundled payment and quality measurement for an episode of care associated with hip and knee replacements to encourage hospitals, physicians, and post-acute care providers to work together to improve the quality and coordination of care from the initial hospitalization through recovery.

CJR Model was implemented and modified through notice and comment rulemaking and published in proposed and final rules. (42 CFR Part 510)

CJR Model began on April 1, 2016 and will run through December 31, 2020. [https://innovation.cms.gov/initiatives/cjr](https://innovation.cms.gov/initiatives/cjr)

Who is participating in CJR?
Working with the CJR Model

- Regulations- Proposed and Final Rules
- Beneficiary Notifications
- Privacy Documents
- Financial Arrangement and Beneficiary Incentives Guidance
- Appeals
- Compliance Enforcement
OCM is an innovative, multi-payer model focused on providing higher quality, more coordinated oncology care. Physician group practices have enter into participation arrangements that include financial and performance accountability for episodes of care surrounding chemotherapy administration to cancer patients. The practices participating in OCM have committed to providing enhanced services to Medicare beneficiaries, such as care coordination and navigation, and to using national treatment guidelines for care. OCM is a five-year model. https://innovation.cms.gov/initiatives/Oncology-Care/ Who is participating in OCM?
Working with OCM

- Participation Agreement
- Amendments
- Dissolution of Practices
- Project Officer for Physician Group Practices
- Compliance Enforcement
Workgroups

- Program Integrity Workgroup
- Electronic Health Records Workgroup
The Federal Coordinated Health Care Office (Medicare-Medicaid Coordination Office) serves people who are dually enrolled in both Medicare and Medicaid, also known as dually eligible individuals or Medicare-Medicaid enrollees.

- Financial Alignment Initiative
  - Capitated Model Team- State Lead
  - Contract Team
Capitated Model

Under the capitated model, CMS, a state, and a health plan enter into a three-way contract to provide comprehensive, coordinated care.

Prior to enrolling or marketing under the capitated model, each health plan must pass a readiness review.

In the capitated model, CMS and the state will pay each health plan a prospective capitation payment.