



Health Law PERSPECTIVES

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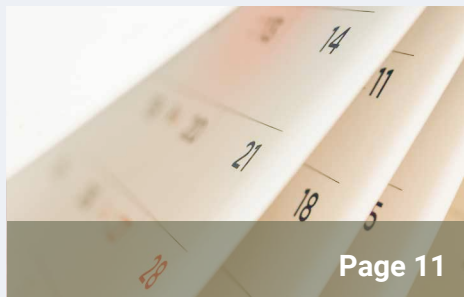
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CMS Issues Draft Hospital Co-Location Interpretive Guidance

by Jordan Kearney and Katrina Pagonis

On May 3, 2019, CMS issued draft guidance on hospital co-location with other hospitals and healthcare facilities, which allows for healthcare entities to share spaces in ways that CMS had previously indicated was not permitted. CMS, DRAFT ONLY – Guidance for Hospital Co-location with Other Hospitals or Healthcare Facilities (May 3, 2019), available at www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO-19-13-Hospital.pdf. CMS is asking for comments on the draft revised policies by July 2, 2019.

PRIOR CMS POLICY

In a webinar on Hospital Co-Location presented by David Eddinger, Technical Director, Hospital Survey & Certification at CMS, on May 5, 2015, Mr. Eddinger stated that it CMS’s position was that Medicare hospital Conditions of Participation (COPs) required that all certified hospital space, departments, services, and locations must be “under the hospital’s control 24/7” based on the requirement that a hospital have a governing body that is legally responsible for the conduct of the hospital. Mr. Eddinger’s position was that the COPs required that a

co-located healthcare entity had to be completely physically separate from any other provider, meaning that (1) there could be no commingling of space such that a patient must travel through hospital space to get to another provider, or through another provider to get to hospital space; (2) space could not be shared by a hospital and another entity; and (3) space could not be “time shared” between a hospital and another provider.

Mr. Eddinger also further noted, regarding another COP addressing the physical environment of hospitals, that while hospital-based entities did not

need to be physically separated from other entities by a fire-rated barrier or fire-rated wall, hospital space would be surveyed “2 hour fire wall to 2 hour fire wall.” If no such barrier existed between the hospital and the co-located entity, the surveyor would include in the survey all space until the required barrier is reached.

DRAFT INTERPRETIVE GUIDANCE ON CO-LOCATION

CMS’s draft interpretive guidance is an attempt to loosen the restrictions on co-location in an attempt to “ensure safety and accountability without being overly prescriptive.” Under the new draft guidance, hospitals would be expressly permitted to co-locate with other hospitals or other healthcare entities. They could be located on the same campus of or in the same building used by another hospital or healthcare facility. The hospital could be co-located in its entirety or only certain parts of the hospital could be co-located with other healthcare facilities. In any situation, when a hospital is co-located with another healthcare entity, each entity is responsible for demonstrating separate and independent compliance with the hospital CoPs.

The draft guidance would allow a hospital and co-located health facility to have “shared spaces,” which are public spaces and public paths of travel that are used by both entities, with both entities individually responsible for compliance with the CoPs in the shared spaces. Examples of public spaces and paths of travel would include public lobbies, waiting rooms, and reception areas (with

separate “check-in” areas and clear signage), public restrooms, staff lounges, elevators and main corridors through non-clinical areas, and main entrances to a building. Where co-located entities share a public path of travel – such as a main hospital corridor with distinct entrances to departments (e.g., outpatient medical clinics, laboratory, pharmacy, etc.) – they would be required to identify, for the public, which healthcare entity is performing the services in which department.

The hospital would still be required to maintain defined and distinct spaces of operations for which it maintains control at all times, including clinical spaces designed for patient care and spaces necessary for the protection and privacy of patients. Co-located entities may not share:

1. **Clinical Care Spaces:** A clinical space is “any non-public space in which patient care occurs.” This includes, but is not limited to, any space within nursing units (including hallways, nursing stations, and exam and procedure rooms located within nursing units), outpatient clinics, emergency departments, operating rooms, post-anesthesia care units, etc. Co-mingling of patients in clinical areas could pose a risk to patient safety for (e.g., because the two entities have different infection control policies) and could jeopardize patients’ right to personal privacy and confidentiality of their medical records.
2. **Spaces Used for Medical Records or Patient Registration/Admission:** Sharing these spaces could

potentially pose a risk to patient privacy because an unauthorized person could gain access to records without consent. Two entities would be able to share a waiting room, but the “check-in” areas must be separate and indicated with clear signage.

3. **Paths through Clinical Care Spaces:** Though co-located entities would be permitted to share public paths of travel, paths through clinical spaces may not be shared. For example, a hallway, corridor, or path of travel through an inpatient nursing unit or through a clinical hospital department (e.g., outpatient medical clinic, laboratory, pharmacy, imaging services, operating room, etc.) may not be shared.

Under the draft guidance, surveyors (and accreditation agencies) would ask for a floor plan to distinguish between the spaces used by the hospital being surveyed and the spaces used by other co-located entities, which must clearly identify which healthcare entities use the spaces. If a surveyor identifies non-compliance in a shared space, the surveyor would be instructed to contact his or her supervisor to file a complaint and seek authorization to conduct a complaint survey of the other co-located facility while still on site. This would result in two separate surveys and two separate survey reports. For accreditation organizations, it would be up to accreditation organization as to whether it will conduct a complaint survey at that time or at a later time.

If you would like more information or need assistance, please contact [Jordan Kearney](#) or [Katrina Pagonis](#) in San Francisco, [Sandi Krul](#) or [David Henninger](#) or [Alicia Macklin](#) in Los Angeles, [David Vernon](#) in Washington D.C., [Amy Joseph](#) in Boston, or your regular Hooper, Lundy & Bookman contact.

CMS’s draft interpretive guidance is an attempt to loosen the restrictions on co-location in an attempt to “ensure safety and accountability without being overly prescriptive.”



What the Supreme Court's *Azar v. Allina* Ruling Means for Health Care Providers

by Kelly Carroll

In a long-awaited decision, on June 3, 2019, the Supreme Court of the United States rejected the government's contention that it is not required to engage in notice-and-comment rulemaking when it imposes an interpretive legal standard under the Medicare Act. Instead, the Court in ***Azar v. Allina Health Services, No. 17-1484 (U.S. June 3, 2019)***, the Supreme Court held in a 7-1 decision authored by Justice Gorsuch¹ that the Medicare Act requires notice-and-comment rulemaking for any establishment of, or change to, a substantive legal standard concerning Medicare benefits or payment, including those that may be viewed as interpretive under the Administrative Procedure Act (APA).

Even the narrow issue decided by the Supreme Court—whether the government could change the standard governing payment to

hospitals that serve a disproportionate number of low-income patients without engaging in notice-and-comment rulemaking—could impact hospitals nationwide to the tune of a few billion dollars.

In *Allina*, the hospitals challenged the Medicare disproportionate share hospital (DSH) adjustments for federal fiscal year 2012, specifically challenging CMS's decision to include inpatient hospital days attributable to Medicare Part C enrollee patients in the numerator and denominator of the Medicare/SSI fraction used to calculate a hospital's DSH payments. This particular challenge

followed years of litigation relating to CMS's inconsistent treatment of Medicare Part C days. Prior to 2004, the agency's standard practice was to exclude Part C days from the Medicare/SSI fraction; in 2004,

the agency attempted to switch course to include Part C days in the Medicare/SSI fraction, but that rule was ultimately vacated.

In 2013, the agency

prospectively adopted a rule to include Part C days in the Medicare/SSI fraction for federal fiscal year 2014 and beyond, and that rule remains the subject of ongoing litigation as to whether it is enforceable substantively.

The *Allina* decision makes clear that, over the past three decades, CMS has been required to provide notice and opportunity for comment when establishing or changing substantive legal standards in Medicare.

¹ Having authored the D.C. Circuit opinion appealed by the government (and affirmed by the Supreme Court's decision), Justice Kavanaugh took no part in the consideration of or decision of this case before the Supreme Court.

The Supreme Court's ruling addresses the agency's attempts to impose the policy espoused in its vacated 2004 rulemaking to a fiscal year in the 2004–2013 time period without using notice-and-comment rulemaking. The Court's decision hinged on the meaning of the statutory phrase "substantive legal standard" within the Medicare Act's notice-and-comment requirements at 42 U.S.C. §1395hh(a)(2). The D.C. Circuit previously found in favor of the hospitals on this point, in an opinion issued by then-Circuit Judge Kavanaugh: "The Medicare Act requires notice-and-comment rulemaking for any (1) 'rule, requirement, or other statement of policy' that (2) 'establishes or changes' (3) a 'substantive legal standard' that (4) governs 'payment for services.' *Id.*

§ 1395hh(a)(2). All four requirements are readily met here." *Allina Health Servs. v. Price*, 863 F.3d 937, 943 (D.C. Cir. 2017). In affirming the D.C. Circuit's judgment, the Supreme Court found that the government failed to offer a lawful excuse for its failure to engage in its statutory notice-and-comment obligations, specifically rejecting the government's suggestion that the Medicare Act's

use of "substantive" should be read as distinguishing from an "interpretive" legal standard, tracking the use of those terms under the APA, and thus exempting the government from any notice-and-comment obligations. The Court rebuffed the government's attempts, finding that the Medicare Act and the APA do not use "substantive" in the same way.

Although the Court affirmed the D.C. Circuit's judgment only under §1395hh(a)(2), and the Court suggests that this decision will have fairly limited impact in terms of requiring that certain policies currently contained in the Provider

Reimbursement Manual be adopted through notice-and-comment rulemaking, the implications for the Supreme Court's decision on Medicare

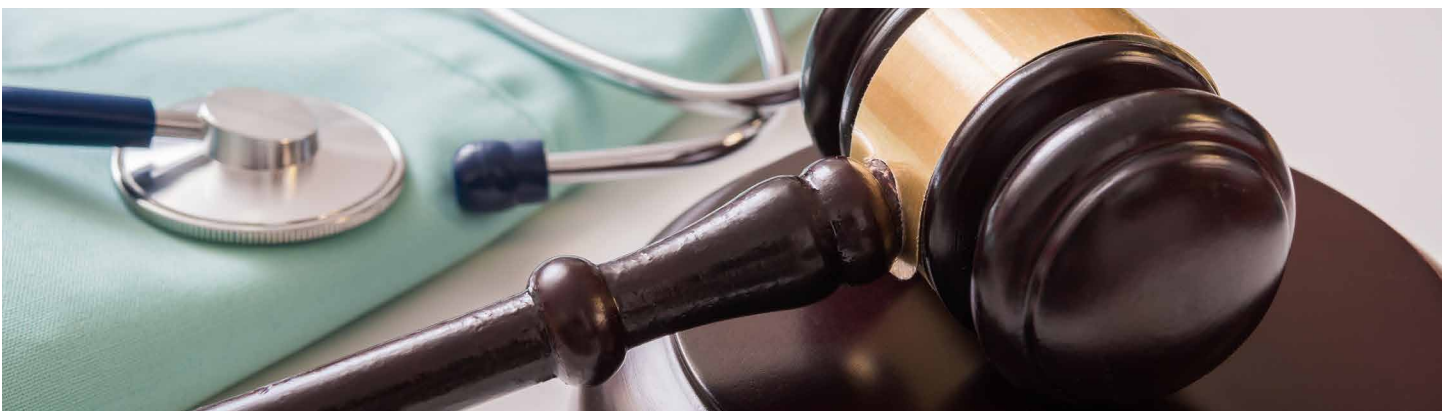
policymaking are important and potentially highly significant. CMS regularly establishes policies that are set forth only in sub-regulatory guidance, whether that takes the form of manual provisions, internet announcements (like the spreadsheet at issue in *Allina*), or answers to frequently asked questions (FAQs). In addition, Local Coverage Determinations (LCDs), which are

Medicare coverage determinations made by Medicare Administrative Contractors (MACs) on behalf of CMS, may be considered substantive legal standards concerning Medicare benefits. The *Allina* decision makes clear that, over the past three decades, CMS has been required to provide notice and opportunity for comment when establishing or changing substantive legal standards in Medicare. This decision likely will aid providers, beneficiaries, and other stakeholders that have been adversely impacted by sub-regulatory guidance and will help ensure that future Medicare policies are imposed only after proper notice and consideration of public comments.

With respect to hospitals' DSH payments, the decision should cause CMS to recalculate hospitals' DSH Medicare/SSI fractions, with Medicare Part C days excluded, for at least federal fiscal year 2012, but likely federal fiscal years 2005 through 2013, at least where hospitals have appealed the issue or the issue is still subject to appeal.

If you would like more information or need assistance, please contact [Kelly Carroll](#) or [Bob Roth](#) in Washington, DC, [Katrina Pagonis](#) in San Francisco, [Lloyd Bookman](#), [Larry Getzoff](#), [John Hellow](#), or [Patric Hooper](#) in Los Angeles, or your regular Hooper, Lundy & Bookman contact.

The Court's decision hinged on the meaning of the statutory phrase "substantive legal standard" within the Medicare Act's notice-and-comment requirements





Foreign Interests and Conflicts of Interest in Research

by Amy Joseph and Kelly Carroll

Institutions that receive certain federal funding for research are required to take steps to identify and manage financial conflicts of interest, including, without limitation, requiring investigators to disclose certain financial relationships, adopting a conflict of interest policy and making such policy publicly available, and providing training to investigators on the topic. Over the past year, government officials and academic research institutions have grown increasingly concerned that foreign countries may be taking advantage of United States-funded research by diverting U.S. intellectual property, and have identified the failure of some investigators to disclose

financial relationships with foreign entities as a related issue. Due to this increased scrutiny, institutions should consider assessing their current conflict of interest program to assess compliance with the applicable regulations.

In March of 2018, the National Institutes of Health (NIH) issued **Notice NOT-OD-18-160, Financial**

Conflict of Interest: Investigator Disclosures of Foreign Financial Interests, as a reminder that disclosures under 42 CFR Part 50 Subpart F (which, as described further below,

requires institutions to take certain steps to identify and manage financial conflicts of interest) must include

disclosures of financial interests received from a foreign institution of higher education or foreign government. In August of 2018, NIH posted a **Statement on Protecting the Integrity of U.S. Biomedical Research** on its website and sent letters to approximately 10,000 institutions, stating that “some foreign entities have mounted systematic programs to influence NIH researchers and peer reviewers,” and identifying three areas of concern: (1) failures by some researchers at NIH-funded institutions to disclose substantial resources from foreign entities, (2) diversion of intellectual property, and (3) sharing of confidential information on grant applications with foreign entities.

In January 2019, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) issued **a letter to Senator Grassley** in response to the senator’s inquiries regarding the growing threat of foreign government interference in taxpayer-funded medical research.¹ The

Over the past year, government officials and academic research institutions have grown increasingly concerned that foreign countries may be taking advantage of United States-funded research

¹ Senator Grassley also made inquiries directly with NIH and with DOJ. See <https://www.grassley.senate.gov/news/news-releases/nih-research-projects-referred-inspector-general-failure-disclose-foreign>.

letter addressed how OIG conducts investigations of foreign interests and integrity of U.S. research, including how OIG, the Department of Justice, the Federal Bureau of Investigation, and NIH coordinate to address such issues. According to OIG's letter to Senator Grassley, NIH recently referred 12 institutions for noncompliance related to research, primarily involving investigators at academic institutions who allegedly failed to disclose foreign affiliations on grant applications.

In addition, Congress recently appropriated funds to OIG to oversee NIH efforts

to ensure the integrity of the grant process.² In February 2019, OIG posted multiple items to its **Work Plan**, reflecting this directive,

Given the additional scrutiny by regulators, institutions should consider a close review of their current conflict of interest policies

including examination and monitoring of financial conflicts of interest reported by grantee institutions, audits of NIH's pre-award and post-award process based on potential risks identified in grant applications, and a review to "determine whether NIH has policies, procedures, and controls in place for ensuring that both foreign and domestic grantees disclose all sources of research support, financial interests, and affiliations."

Of course, while there has been a recent focus on foreign governmental activity, the potential for conflicts of interest impacting objectivity in the research context has been a source of scrutiny and regulation for quite some time. Although relationships between research institutions, investigators, and industry may foster innovation,

such relationships also create the potential for bias. The issue recently has garnered national attention more generally due to multiple recent high profile news stories revealing the failure of researchers to disclose financial interests with certain companies in publications. Along these lines, a **study published in JAMA in November 2018** found that potential conflicts of interest were only disclosed in 37% of the articles published by the 100 physicians receiving the highest compensation from device manufacturers (based on data available on the CMS Open Payments website).

Although scrutiny of conflict of interest protocols has increased recently, the applicable rules have not changed at this point. Pursuant to 42 CFR Part 50, Subpart F, institutions that apply for or receive Public Health Service (PHS) funding for research (and investigators and other key research personnel and sub-recipients, by virtue of implementation of the regulations by institutions) are required to take a number of actions, including, without limitation, requiring disclosure by investigators of any significant financial interest (SFI) for the institution's review and evaluation, determination of whether the SFI constitutes an actual or perceived financial conflict of interest (FCOI), development of a FCOI management plan, and submission of a FCOI report to the PHS-awarding component, including an explanation of how the conflict has been managed, reduced, or eliminated.³ These regulations

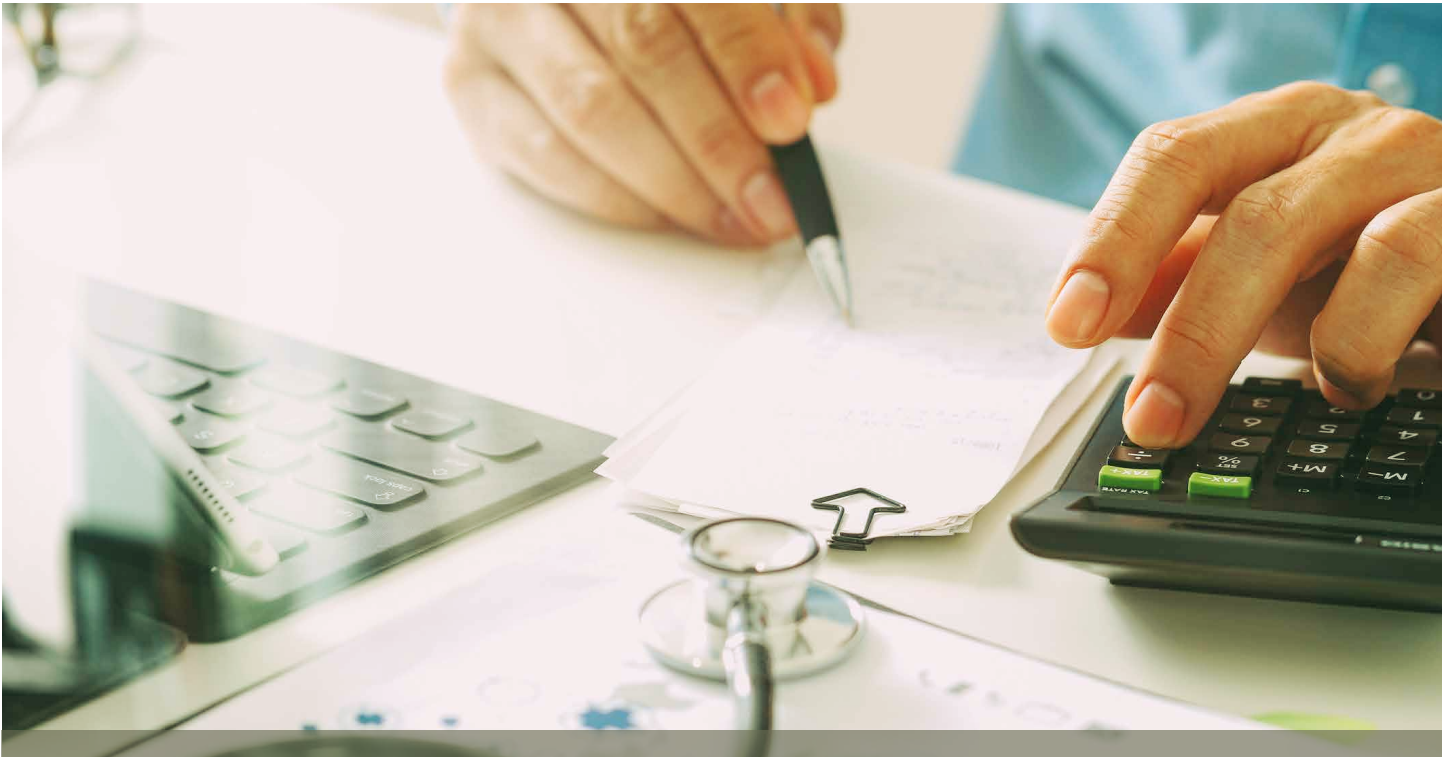
exclude from the definition of SFI income received from an institution of higher education as defined in 20 USC 1001(a) or a federal, state or local government agency, however this exclusion does not extend to include foreign institutions or governments.

Increased scrutiny likely will continue in the months to come, along with a potential increase in enforcement activity and regulatory guidance. Given the additional scrutiny by regulators, institutions should consider a close review of their current conflict of interest policies, if they have not done so recently, to assess how well their process currently works and whether any revisions are needed to ensure conflicts of interest are appropriately disclosed and managed. Some additional proactive steps could be to consider additional training regarding what constitutes an SFI and other requirements under the institution's COI policy, posting frequently asked questions to assist investigators in navigating the process, or otherwise finding ways to make expectations and consequences clear, as well as building in more robust auditing to periodically assess compliance with the institution's policies and to ensure the policies are uniformly and consistently implemented.

Hooper, Lundy & Bookman's Academic Medical Center/Teaching Hospital Working Group provides assistance to health care providers in all aspects of research compliance. For more assistance, please contact [Amy Joseph](#) in Boston, [Kelly Carroll](#) in Washington, D.C., and [Andrea Frey](#) or [Katrina Pagonis](#) in San Francisco.

² See Departments of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (Pub. L. No. 115-245).

³ *Responsibility of Applicants for Promoting Objectivity for which PHS Funding is Sought* (42 CFR Part 50, Subpart F, 76 Fed. Reg. 53256 (Aug. 25, 2011)). The U.S. Food and Drug Administration (FDA) and the National Science Foundation (NSF) also impose conflict of interest requirements, which include different requirements and are triggered under different circumstances. Notably, pursuant to Section 2034 of the 21st Century Cures Act, HHS is required to review the conflict of interest requirements of various funding agencies, for potential harmonization moving forward.



MACs Improperly Eliminate Pass-Through Treatment of Hospital Allied Health Program Costs

by *Arthur Peabody*

Hooper, Lundy & Bookman, P.C. (HLB) wants to make hospitals aware of current adjustments being imposed by certain MACs denying pass-through treatment of allied health program costs, including nursing, pharmacy and pastoral care. The denial of pass-through treatment is based on the view of some MACs that any administrative involvement by a home office means that the hospital does not appropriately incur the costs of the allied health program and do not, as a result, comply with 42 C.F.R §413.85(f). We expect that

this improper practice could spread to other MACs.

Reclassification of these costs to the Administrative & General cost center may mean that a hospital will receive no payment for the costs of its allied health programs. For health systems with multiple hospitals, the losses can be significant and the financial impact severe. Direct action, such as properly protesting the potential denials of these costs in the Medicare cost report and filing a PRRB appeal for each affected cost reporting

period, may be required to address this improper denial of pass-through treatment.

HLB is prepared to assist hospitals with this issue. If you would like more information or need assistance, please contact [Arthur Peabody](#), [Kelly Carroll](#), [Bob Roth](#), or [David Vernon](#) in DC, [Katrina Pagonis](#) in San Francisco, [Lloyd Bookman](#), [Nina Marsden](#) or [Alicia Macklin](#) in Los Angeles, [Amy Joseph](#) in Boston, or your regular Hooper, Lundy & Bookman contact.

The denial of pass-through treatment is based on the view of some MACs that any administrative involvement by a home office means that the hospital does not appropriately incur the costs of the allied health program

GOVERNMENT & POLICY WATCH

Congressional

BIPARTISAN MEDICARE PART D DRUG PRICING DRAFT RELEASED

On May 23, leaders of the House Ways and Means and Energy and Commerce Committees released a **draft bill** to cap out-of-pocket costs for Medicare Part D beneficiaries. The draft would set seniors' caps based on the current catastrophic threshold in Medicare Part D bringing the government's share of catastrophic coverage from 80 percent to 20 percent over four years, gradually shifting more costs onto plans. The Committees received feedback earlier this month, and will likely continue work in this area throughout the summer.

PANDEMIC PREPAREDNESS BILL SENT TO PRESIDENT

On June 4, the House of Representatives passed the **Pandemic and All-Hazards Preparedness and Advancing Innovation Act (S. 1379)**, legislation to reauthorize the Department of Health and Human Services' (HHS) efforts to respond to disasters and threats from emerging infectious diseases and chemical or biological agents. The legislation now heads to the President to sign, which is expected in the coming days.



Administration

PACE FINAL RULE RELEASED

On May 28, the Centers for Medicare and Medicaid Services (CMS) released the **final rule** for Programs of All-Inclusive Care for the Elderly (PACE). The **rule** has been long awaited and provides more administrative and regulatory flexibilities, such as letting one member of the care team serve in multiple roles.

VETERANS COMMUNITY CARE PROGRAM RULE RELEASED

On June 4, the Department of Veteran's Affairs (VA) released its **final rule** for the Veterans Community Care Program, implementing the criteria for determining when covered veterans may elect to receive necessary hospital, medical and extended care services from non-VA entities or providers. The rule took effect on June 6.

ADMINISTRATIVE BURDEN RFI RELEASED

On June 6, CMS released a **request for information** (RFI) on Reducing Administrative Burden to put Patients over Paperwork. CMS is seeking further comment on changes to rules, policies, and procedures that would shift more of clinicians' time and resources from reporting, to providing quality care. Comments are due August 12.

FIRM NEWS

Things happening at Hooper, Lundy & Bookman



HOOPER, LUNDY & BOOKMAN ACCEPTED AS A NEW LEGAL RESOURCE FOR THE CENTER FOR TELEHEALTH AND EHEALTH LAW

Hooper, Lundy & Bookman is now an affiliate of the Robert J. Waters Center for Telehealth and e-Health Law ("CTeL") after Jeremy Sherer, co-chair of HLB's

Digital Health Task Force, was recently named a member of the CTeL Legal Resource Team. Legal Resource Team members are experienced telehealth counselors who advise CTeL's staff, its Board of Directors, and its members regarding issues of telehealth law.

Founded in 1995, **CTeL** is a leading national organization on legal and regulatory issues impacting the advancement of telehealth.

SHAYNA SHARIM AND ERIN SCLAR JOIN HOOPER, LUNDY & BOOKMAN AS 2019 SUMMER ASSOCIATES

Hooper, Lundy & Bookman is very pleased to welcome summer law associates Shayna Sharim and Erin Sclar. Erin, who attends UC Hastings, will be in our San Francisco office and Shayna, who attends USC, will be in our Los Angeles office. Summer law associates work with some of HLB's most senior practitioners who share their knowledge through both formal and informal mentoring and training.



Shayna Sharim



Erin Sclar



Robert Miller

CONGRATULATIONS ROBERT MILLER

Congratulations to Robert Miller who has been appointed as Vice Chair for the Publications Book Editorial Board for the American Bar Association Health Law Section.

CONGRATULATIONS ERIC CHAN

Congratulations to Eric Chan who has been selected to be a member of the Diversity in the Profession Committee for the Los Angeles County Bar Association



Eric Chan



CALENDAR

DATE	EVENT
June 9	HCCA 2019 Research Compliance Conference, Orlando, FL Amy Joseph presented <u>Identifying and Managing Physician Conflicts of Interest in the Research Context</u>
June 13-14	CTeL Telehealth Spring Summit 2019 Jeremy Sherer co-presented <u>Telebehavioral Health: Standards, Reimbursement and Interstate Practice.</u>
June 14	HCCA 2019 Orange County Regional Conference Charles Oppenheim and Alicia Macklin present <u>Regulatory Update</u>
June 17-18	Northeast Regional Telehealth Conference Jeremy Sherer and Amy Joseph co-present <u>Legal and Regulatory Issues in Telehealth.</u> Jeremy Sherer serves as a panelist on <u>Plenary Panel - National and Regional Telehealth Policy Perspectives: Key Trends and Considerations.</u>
July 9	HLB-Wolters-Kluwer Webinar Series (Part 3) Bob Roth, Joe LaMagna, Amy Joseph, Andrea Frey and Jeremy Sherer present <u>The First Half is In the Books – What’s In Store for the Rest of 2019</u>
July 14-17	CAHF Summer Conference, San Diego, CA Mark Reagan and Jeremy Sherer co-present Telehealth for SNFs Mark Johnson and Scott Kiepen co-present Fraud and Abuse Legal Update
July 17	HLB Webinar David Vernon presents Hot Topics in Graduate Medical Education Reimbursement
November 10-13	CAHF Annual Conference, Palm Springs, CA Mark Johnson presents

Weekly Trivia: Where is the “Little White House located”
[Click here](#) for the answer.

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