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Application Due Soon for Two New Rounds of Residency Slot Redistribution

By David Vernon

On April 24, 2018, the Centers for Medicare & Medicaid Services (CMS) issued its Hospital Inpatient Prospective Payment Systems (IPPS) proposed rule for Fiscal Year 2019 (Proposed Rule). Contained within the Proposed Rule was a notice from CMS of the closure of two teaching hospitals and the opportunity for hospitals to apply for the newly available graduate medical education resident slots under Section 5506 of the Affordable Care Act (ACA).

Background and Balanced Budget Act of 1997

In 1997, in an effort to limit the cost of health care, in part related to the cost of training physicians, Congress passed the Balanced Budget Act of 1997 (BBA '97). BBA '97 instituted a cap on the number of allopathic and osteopathic residents for which Medicare would reimburse. The cap was limited to the number of full-time equivalent (FTE) residents training at a hospital in 1996. The cap is difficult to grow; although there are certain exceptions. Still, the residency cap has significantly impacted direct graduate medical education (DGME) and indirect medical education (IME) reimbursement to teaching hospitals and academic medical centers in the United States.

Affordable Care Act Changes to Residency Slot Redistribution

Despite the residency cap, in the years following BBA '97, teaching hospitals continued to grow residency programs and training opportunities to fill community needs. Due to the cap, unless fitting in an exception, the training of these residents would not be paid for by Medicare. As a result, teaching hospitals sought ways to capture additional residency slots.

Leading up to the enactment of the ACA, two ways in which this recapturing of slots issue presented itself was if (1) a teaching hospital was not using all of its slots or (2) a teaching hospital closed and the slots were "lost." The ACA addressed these two situations under Sections 5503 and 5506. Under Section 5503 of the ACA, 42 U.S.C. § 1395ww(d)(5)(B)(v) was amended and subsection (h)(8) was added to provide for the reduction in FTE resident caps for IME and DGME, respectively, for certain hospitals training fewer residents than their caps and to authorize the redistribution of those slots to other qualified hospitals.

Section 5506 of the ACA amended 42 U.S.C. § 1395ww(h)(4)(H) to add new clause (vi), instructing the Secretary to establish a process by regulation, to redistribute residency slots after a teaching hospital closes. This process established a way for the Secretary to permanently increase the FTE resident caps for certain hospitals, so that the closed hospitals' resident slots would no longer be "lost." By statute, the process for distributing the residency slots prioritizes hospitals in certain geographic areas, and also provides that a preference be given within each priority category to hospitals that are members of the same affiliated group with the closed hospital. The priority order is: first, to hospitals located in the same, or a

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contiguous, core-based statistical area (CBSA) to the closed hospital; second, to a hospital located in the same state as the closed hospital; third, to a hospital located in the same region as the closed hospital; and fourth, if slots still have not been distributed under the first three categories, to qualifying hospitals in accordance with the criteria established under Section 5503 of the ACA, paragraph 8, concerning the distribution of additional residency positions.

Moreover, as described within the Federal Register concerning the implementation of Section 5506, CMS articulated a Ranking Criteria, whereby within each of the first three statutory priority categories (that is, same or contiguous CBSAs, same state, and same region), CMS would assign slots first to hospitals that fall within the first ranking category, before assigning slots to those hospitals that fall within the second ranking category, and then to those hospitals that fall within the third ranking category. See 75 Fed. Reg. 71799, 72216 (Nov. 24, 2010); 77 Fed. Reg. 53258, 53434 (Aug. 31, 2012); 79 Fed. Reg. 50122-50134 (Aug. 22, 2014).

The Ranking Criteria currently contains eight Ranking Criterion. The Ranking Criteria prioritize: assumption of and continued operation of an entire program from the closed hospital (One); use of slots received as part of the most recent affiliation agreement with the closed hospital to continue to train at least those residents it was training (Two); and where the hospital took in displaced residents and will use those slots to continue training the displaced residents until they complete their training, as well as will maintain those slots to continue training others in the same programs as the displaced residents (Three).

For the remaining five criteria, the Ranking Criteria prioritize the planned use of the new slots for primary care or otherwise prioritized residency programs over nonprimary care programs: geriatrics residency program (Four); if located in a Health Professional Shortage Area (HPSA), primary care or general surgery residency program (Five); if not located in a HPSA, primary care or general surgery residency program (Six); some used for a primary care or general surgery program, but the program does not meet Ranking Criterion 5 or 6 because the hospital is also separately applying under Ranking Criterion 8 for slots to establish or expand a nonprimary care or non-general surgery program (Seven); and the hospital will use the slots to establish or expand a nonprimary care or a nongeneral surgery program (Eight).

In addition to considering the ranking categories and criteria, Section 5506 requires CMS to only award slots to hospitals where the Secretary "determines the hospital has demonstrated a likelihood of filling the positions made available under [42 U.S.C. § 1395ww(h)(4)(H)(vi)] within 3 years."

Section 5506 – Rounds 11 and 12

As noticed in the Proposed Rule, CMS learned of the closure of two teaching hospitals: Affinity Medical Center, located in Massillon, OH – 22.36 IME and 22.48 DGME cap slots available (Round 11) and Baylor Scott & White Medical Center—Garland, located in Garland, TX – 12.52 IME and 13.53 DGME cap slots available (Round 12), and is seeking applications in order to redistribute the residency slots. The application period for each of these hospitals is 90 days following the Proposed Rule issuance date of April 24, 2018. As such, applications are due no later than July 23, 2018.

A separate application is required for each closure, should a hospital wish to apply for slots from Rounds 11 and 12. The applications must be received in hard copy by the CMS Central office no later than July 23, 2018, as postmarking by this date is not sufficient. Applicants are also strongly encouraged to email CMS a specific message as set forth in the Proposed Rule, notifying CMS that the application is on the way and providing applicant contact information.

If you are interested in applying for Rounds 11 and/or 12, or would like further guidance or information, please contact David Vernon or Marty Corry in Washington, D.C. at 202.580.7700, or John Hellow in Los Angeles at 310.551.8100.

California Governor Signs Far-Reaching Consumer Privacy Legislation

By Steve Phillips and Jeffrey Lin[1]

On June 28, 2018, the California Legislature passed and California Governor Jerry Brown signed Assembly Bill 375 (AB 375), known as the California Consumer Privacy Act (CCPA) of 2018. The CCPA will establish new privacy rights for California residents and new obligations for California businesses beginning in January 1, 2020.

The CCPA has drawn comparisons to the European Union's General Data Protection Regulation (GDPR), because it establishes many of the privacy protections contained in the GDPR. Californians for Consumer Privacy has said it will withdraw its ballot measure for a similar California Consumer Privacy act because of the CCPA's passage.[2]

Under the CCPA, California residents will have the right to request that a business provide them with the personal information the business collects about the resident requesting such information. In addition, individuals can request that a business stop selling their personal information. Although the CCPA excludes from its jurisdiction patient health information defined under the California Medical Information Act (CMIA) and the Health Insurance Portability and Accountability Act (HIPAA), health care providers would still be subject to the law because it applies to any resident of California, including employees and other workforce members of a business. Thus, all information providers have on their employees, contractors, and other workforce members would be subject to the CCPA.

Summary of the California Consumer Privacy Act (CCPA)

What is the CCPA?

- The California Consumer Privacy Act requires California businesses to provide California residents with the right to know how their personal information is collected, sold, or disclosed by certain businesses, and the right to prevent businesses from selling their personal information.

Who is covered by the CCPA?

- The CCPA's privacy obligations apply to "businesses," defined as legal entities that (1) do business in California; (2) collect or sell personal information; and (3) either: (A) have annual gross revenues exceeding $25 million (to be adjusted to reflect changes in the Consumer Price Index), (B) derive 50 percent or more of annual revenues from selling consumers' personal information, or (C) buy, sell or share for commercial purposes "the personal information of 50,000 or more consumer, households, or devices." Civ. Code § 1798.140(c).
- The CCPA's privacy rights apply to "consumers," which are defined by the law as California residents, which in turn are defined as (1) all individuals in California for other than a temporary purpose and (2) everyone domiciled in California who is not in the state for a temporary purpose. 18 CCR § 17014. There is no exclusion in the definition for personal information an employer maintains regarding its employees and other workforce members.

What information does the CCPA regulate?

- The CCPA regulates "personal information," defined as any information that could reasonably be linked to a consumer, including but not limited to, personal identifiers, commercial information, biometric information, internet activity information, and employment related information. 1798.140(o)(1).
- Personal information does not include "publicly available" information or information available from federal, state, or local government records. 1798.140(o)(1)(K)(2).
- The CCPA does not apply to protected or health information collected by a covered health entity governed by CMIA or HIPAA. 1798.145(c).

What activities does the CCPA apply to?

- Collecting information pertaining to a consumer through buying, selling, gathering, obtaining, or any other means. 1798.140(e).
- "Selling, renting, releasing, disclosing, disseminating, making available, transferring, or otherwise communicating" orally, electronically, or in writing a consumer's personal information to another business or third party for monetary or other valuable consideration. 1798.140(t)(1).

What are the different rights businesses and consumers will have under the CCPA?

- **Businesses**
  - A business can offer financial incentives for the collection of personal collection as long as consumers consent to opt-in. 1798.125(b)(1).
- **Consumers**
  - The right to request a business delete any personal information about the consumer which the business has collected. 1798.105(a).
  - The right to request a business collecting personal information disclose: (1) the categories of personal information collected, (2) the category of sources from which the personal information is collected, (3) the business or commercial purpose of the personal information, (4) the categories of third parties the business has shared the information with, and (5) the specific pieces of information a business has collected from a consumer. 1798.110.
  - The right to request a business selling personal information about the consumer disclose: (1) the categories of personal information sold; (2) the categories of personal information the business sold and the categories of third parties who received it; and (3) the categories of personal information that the business disclosed about the consumer for a business purpose. 1798.115.

What other obligations will businesses have under the CCPA?

- If a consumer requests a business not to sell his or her personal information, the business cannot do so. § 1798.120(c). In addition, a business cannot sell personal information if it has actual knowledge the consumer is less than 16 years of age unless the consumer, if between 13 and 16 years of age, consents or the consumer's parent or guardian, if the consumer is less than 13 years of age, consents. 1798.120(d).
- A business must secure personal information from breaches and unauthorized uses and disclosures. See 1798.150(a)(1).
- A business cannot discriminate against consumers for exercising their rights under the CCPA by charging different rates or changing quality. 1798.125(a)(1).
- A business must establish two or more methods for submitting requests for information. This includes a toll-free telephone number and a Web site address if the business has an Internet Web site. 1798.130(a)(1).
- In its online privacy policies, the business must provide a description of the consumer's rights, a list of categories

of personal information it has collected about consumers, and, whether it has collected, sold, or used personal information for business purposes. § 1798.130(a)(5). In addition, it must have a "clear and conspicuous" link on the business' Internet homepage titled "Do Not Sell My Personal Information" that allows consumers to opt out of the sale of their § 1798.135(a)(1).

What are the consequences of violating the CCPA?

- Violators of the CCPA are liable for a civil penalty under Section 17206 of the Business and Professions Code in a civil action brought by the Attorney General. Violators may also be liable for civil penalties of up to $7500 per violation. 1798.155(a)-(b).
- If a consumer's personal information is subject to a security breach because of the business's violation of the duty to have reasonable security procedures, then the consumer can sue for civil damages between $100 and $750 per consumer per incident or actual damages, whichever is greater. 1798.150(a)(1).

What can businesses do to avoid violating the CCPA?

- Businesses can ask the California Attorney General for guidance on complying with the CCPA. 1798.155.
- A business disclosing personal information to a service provider is not liable if the service provider violates the CCPA and the business has no actual knowledge to believe the service provider intended to commit a violation. If the service provider discloses personal information to the business and the business violates the CCPA, the service provider is not liable if it has no actual knowledge to believe the business intended to violate the CCPA. 1798.145(h).

Conclusion

The CCPA will place significant new obligations on health care to protect the personal information of employees, patients and other California residents. Businesses will have to not only inform consumers of their rights, but also be subject to penalties for violating the CCPA. Hooper, Lundy & Bookman's health privacy attorney's will continue monitoring the effects of the CCPA.

For more information please contact Steve Phillips, Paul Smith or Jeffrey Lin in San Francisco at 415.875.8500; Amy Joseph in Boston at 617.532.2702; or David Vernon in Washington, D.C. at 202.580.7713.

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[1] Jeffrey Lin is a current summer associate at Hooper, Lundy & Bookman and a law student at U.C. Berkeley School of Law.

[2] Bryan Anderson, Sweeping California consumer privacy bill approved by Jerry Brown, The Sacramento Bee (June 28, 2018, 1:28 pm), https://www.sacbee.com/news/politics-government/capitol-alert/article213993229.html

Connecticut Permits Prescribing Limited Controlled Substances via Telemedicine

by Jeremy D. Sherer and Jennifer Hansen

Connecticut Governor Dannel Malloy has signed SB 302, a new law reversing Connecticut's prohibition on prescribing controlled substances via telemedicine. SB 302 took effect July 1, 2018.

SB 302 and Prescribing Controlled Substances Via Telemedicine

Under SB 302, qualified telehealth providers in Connecticut can prescribe certain controlled substances via telemedicine, within each provider's scope of practice and in accordance with the standard of care applicable to the profession, to treat individuals with defined psychiatric disabilities or substance use disorders. The new law allows some controlled substances to be prescribed for medication-assisted treatment, but does not allow opioids to be prescribed via telemedicine. Previously, Connecticut prohibited prescribing any Schedule I, II, or III controlled substances via telemedicine. SB 302 allows Schedule II and Schedule III controlled substances to be prescribed via telemedicine, except for opioids, and requires providers prescribing such controlled substances utilizing telehealth technologies to do so via electronic prescription.

Federal Law and Prescribing Controlled Substances Via Telemedicine

Even with SB 302's passage, there are still important considerations for Connecticut providers under federal law. The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act), which prohibits providers from prescribing controlled substances without conducting an in-person examination of the patient unless an exception applies, remains in effect. While there are telemedicine exceptions to the Ryan Haight Act, they are narrow and restrictive. For a provider to prescribe controlled substances via telemedicine in accordance with the most commonly used exception, the patient must be in the physical presence of a DEA-registered practitioner, or located at a DEA-registered health care facility (unless, for example, the provider is an employee or contractor of the Department of Veterans Affairs or the Indian Health Service). The telemedicine provider treating the patient must only issue the prescription for a legitimate medical purpose in the usual course of their professional practice acting in accordance with applicable State law.

Notably, the DEA has previously committed to creating a telemedicine registration process that would allow providers to prescribe controlled substances via telemedicine more broadly, but it has not issued proposed or final rules yet. The ongoing opioid epidemic has created pressure to compel the DEA to develop regulations creating the telemedicine registration, and Congress has considered establishing a statutory deadline for the DEA to promulgate regulations implementing a special telemedicine registration process. As it stands, however, the more restrictive telemedicine exceptions described above, such as that requiring the physical presence of a DEA-registered practitioner or the patient being at a DEA-registered health care facility, must be satisfied for providers to prescribe controlled substances via telemedicine.

Other Changes

SB 302 amends the definition of "telehealth provider" to include registered nurses and pharmacists, within the scope of practice and in accordance with the standard of care applicable to each profession, expanding the categories of providers who can provide services via telemedicine under Connecticut law. It also modifies Connecticut's informed consent standards for telemedicine encounters, requiring telehealth providers to obtain the patient's informed consent before the initial telehealth interaction between the patient and the telehealth provider, and allowing that consent to apply to subsequent telehealth interactions. Previously, Connecticut required telehealth providers to obtain the patient's informed consent at the time of each telehealth interaction.

Practice-Oriented Takeaways

Connecticut telehealth providers can now prescribe certain Schedule II and Schedule III controlled substances to treat individuals with psychiatric disabilities or substance use disorders, including by way of medication-assisted-treatment, as long as such providers comply with scope of practice and standard of care applicable to the profession. However, this does notinclude opioids, and providers must remain in compliance with federal law under the Ryan Haight Act and State scope of practice laws. Connecticut's definition of "telehealth provider" now includes registered nurses and licensed pharmacists providing services within the scope of practice and standard of care applicable to each profession. Connecticut telehealth providers can obtain a patient's informed consent before their first telehealth encounter with the patient, and apply that informed consent to subsequent telehealth treatments.

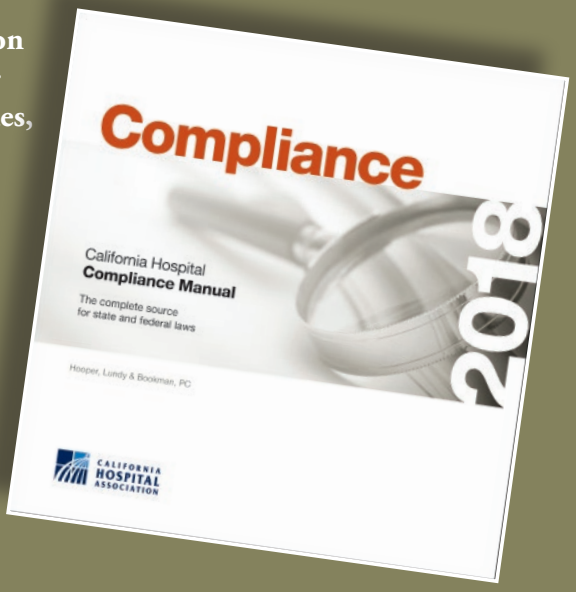
For more information, please contact Jeremy Sherer in Boston at 617.532.2705, Jennifer Hansen in San Diego at 619.744.7310, Steve Phillips in San Francisco at 415.875.8508, Alicia Macklin in Los Angeles at 310.551.8161, or Bob Roth in Washington, D.C. at 202.580.7701.

CALENDAR

July 11	**CHA Managing Patients with Behavioral Health Needs in Acute and ED Settings, Pasadena, CA** Steve Lipton presents.
July 12	**California Behavioral Health Directors Association, Sacramento, CA** Steve Lipton presents *EMTALA - A dialogue on Federal EMTALA rules and the LPS Act*
July 26	**CHA Managing Patients with Behavioral Health Needs in Acute and ED Settings, Sacramento, CA** Steve Lipton presents
August 2	**Quality Care Health Foundation (QCHF) DON/Nurse Leadership Training, Ontario, CA** Mark Johnson presents *Informed Consent*
Sept 5	**SAVE THE DATE: Hooper, Lundy & Bookman's Managed Care Seminar, Berkeley, CA**
Sept 6	**SAVE THE DATE: Hooper, Lundy & Bookman's Managed Care Seminar, Los Angeles, CA**
Oct 7-10	**AHCA/NCAL 69th Annual Convention & Expo, San Diego, CA** Mark Johnson presents
Oct 9, 16	**SAVE THE DATE: Hooper, Lundy & Bookman's Annual Medical Staff Seminar, Oakland, Los Angeles, CA** Jennifer Hansen, Jodi Berlin, Ross Campbell, Katherine Dru, Andrea Frey, Laurence Getzoff, Harry Shulman, Catherine Wicker, and Ruby Wood present
Nov 4-7	**HCCA 4th Annual Healthcare Enforcement Compliance Conference, Washington, DC** Precious Gittens co-presents *401 Managing Your Organization's Response to a Federal Government Investigation*
Nov 7	**4th Annual North Country Telemedicine Conference, Glens Falls, NY** Jeremy Sherer and Amy Joseph co-present *Telemedicine Law 101*

2018 California Hospital Compliance Manual Now Available

The California Hospital Association (CHA) has released the 2018 Edition of the California Hospital Compliance Manual, the complete source for state and federal laws. The manual focuses on high-risk compliance issues, and has been updated to address:



- **The federal Tax Cuts and Jobs Act of 2017, which imposes an excise tax on certain executive compensation and changes the computation of unrelated business taxable income.**
- **The California Department of Public Health's new Centralized Applications Unit for processing applications for changes in beds, services, ownership, etc.**
- **The Office of Inspector General's revised Stark Self-Referral Disclosure Protocol, new mandatory forms, and required financial analysis and reports.**

Written by Hooper, Lundy & Bookman, PC, attorneys and CHA, the manual focuses on key components of an effective compliance program. The manual features 700 pages of content and is the proven must-have for compliance officers, CFOs, and legal counsel. To order the new manual or for more information, visit www.calhospital.org/compliance.

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