



June 2017

## California 2017-18 Budget Prepares to Discontinue the CCI, Gears Up for AB 72, Increases SNF Staffing Ratios

The 2017-18 California State Budget, enacted on June 27, includes a number of significant health care program changes. Following is a summary of some of the more significant changes:

- Coordinated Care Initiative.** Under the CCI, people eligible for both Medicare and Medi-Cal receive medical, behavioral health, long term care services and support, and home and community-based services coordinated through a single health plan. The law creating the CCI pilot, specifically states that it will be discontinued in the next fiscal year if found to be ineffective from a cost perspective. Citing "lessons learned" from the pilot, the current budget act extends the CCI duals demonstration pilot through December 2019.
- Proposition 56.** The Budget includes funding to support new growth in Medi-Cal for expenditures for supplemental provider payments for physician services, dental services, women's health, Intermediate Care Facilities for the Developmentally Disabled, and HIV/AIDS waiver providers. The funding for supplemental provider payments are subject to federal approval, and contingent on continued stability in federal Medicaid funding.
- Restoration of Medi-Cal Dental and Vision Benefits.**
- Skilled Nursing Facility Staffing Ratios.** The Budget includes an increase in the minimum number of direct care services hours in skilled nursing facilities from 3.2 to 3.5 hours per patient day, effective July 1, 2018. It also specifies that a minimum of 2.4 hours per patient day must be provided by certified nurse assistants. This change allows for waivers of the direct care service hour requirements when there is a shortage of available and appropriate health care professionals, according to the DHCS.
- Major Risk Medical Insurance Fund Abolished.** According to the budget summary, the Affordable Care Act reduced the need for the MRMI high-risk pool because of its ban on denied coverage for pre-existing conditions. The remaining fund balance will be transferred to the newly established Health Care Services Plan Fines and Penalties Fund to fund MRMIP and the Medi-Cal program.
- Children's Health Insurance Program (CHIP) Reauthorization** - To extend the CHIP program beyond September 2017, Congress must pass legislation. Given the uncertainties around what actions Congress may take, the Budget assumes the program is reauthorized but at the non-enhanced federal matching percentage of 65% effective October 1, 2017, and includes General Fund costs of \$396.9 million
- Managed Care Organization Tax** - Chapter 2, Statutes of 2016, Second Extraordinary Session (SBx2 2), authorized a tax on the enrollment of Medi-Cal managed care plans and commercial health plans. This tax funds the nonfederal share of Medi-Cal managed care rates for health care services provided to children, adults, seniors and persons with disabilities, and persons eligible for both Medi-Cal and Medicare.
- Managed Care** - AB 72. The Department of Managed Health Care budget includes funding for 16 new posi-

### In This Issue

- California Budget Summary
- Nuances of Clinically Integrated Networks
- Bankrupt Lab Sues Hospitals & Physicians

tions for implementing AB72 (2016), which prohibits “surprise” balance billing.

- **Hospital Quality Assurance Fee Extension.** On November 8, 2016, voters passed Proposition 52, which amends the state Constitution to permanently extend the existing Hospital Quality Assurance Fee. The fee was due to sunset on December 31, 2017.
- **AB 85 Redirection of County Savings.** Chapter 24, Statutes of 2013 (AB 85), modified the 1991 Realignment Local Revenue Health Account distributions to capture and redirect savings counties are experiencing from the implementation of federal health care reform. County savings are estimated to be \$585.9 million 2016-17 and \$688.8 million in 2017-18. The Budget also includes an adjustment of \$255.6 million to account for actual county savings based on the reconciliation of the 2014-15 fiscal year. The Budget assumes reimbursement of this amount from the counties in 2017-18. The General Fund savings are reflected in the CalWORKS program within the Department of Social Services’ budget.
- **Drug Medi Cal Organized Delivery System Pilot.** The Budget includes funding for a five-year pilot program for participating counties to use an organized delivery system to provide substance use disorder services to eligible Medi-Cal beneficiaries. Seven counties began providing services in 2016-17 and an additional 9 counties are anticipated to begin providing services in 2017-18.
- **DSH.** Medi-Cal DSH calculation is revised.
- **21st Century Cures Act.** Authorizes DHCS to enter exclusive and non-exclusive contracts with organizations to implement and administer 21st Century Cures Act grants.

For more information, text of the main health care trailer bill, SB 97, can be found here: [http://leginfo.ca.gov/faces/billNavClient.xhtml?bill\\_id=201720180SB97](http://leginfo.ca.gov/faces/billNavClient.xhtml?bill_id=201720180SB97).

## Clinical Integration: Decreasing Costs And Improving Care (Legally)

by Kevin Royer

Clinical Integration involves collaboration among physicians and other health care providers to help ensure higher quality, better coordinated and more efficient services for patients. Clinical integration includes both horizontal integration (coordination at the same stage of delivery of care) as well as vertical integration (the coordination of services at different stages).

Clinical integration is achieved through clinically integrated networks (CINs). CINs share similar goals with other entities such as Accountable Care Organizations (ACOs), Patient Centered Medical Homes (PCMHs), Physician Hospital Organi-

zations (PHOs) and independent practice associations (IPAs). However, there are significant differences. ACOs focus on care improvement for an entire patient population through various health care delivery systems; PCMHs focus on care improvement for primary care services; and IPAs and PHOs generally engage in financial integration through risk-sharing in order to legally be able to jointly negotiate rates on behalf of their participating providers.

CINs, by contrast, may be broader than ACOs and PCMHs in that CINs generally focus on all patient populations and all healthcare services. Further, unlike PHOs and IPAs, CINs can jointly negotiate fees under certain circumstances by integrating clinically without financial integration. PHOs and IPAs must financially integrate in order to be able to engage in joint negotiation on behalf of their provider networks.

The success of clinical integration depends on how effectively the CIN can achieve clinical integration. The following are examples of key components:

- (1) *Legal Options*-selecting the best organizational structure and operational approach;
- (2) *Physician Leadership*-maintaining a robust physician leadership and permitting them to integrate clinical expertise into the CIN’s governance structure;
- (3) *Participation Criteria*-clarifying expectations through participation agreements with participating providers and groups;
- (4) *Performance Improvement*-establishing the baseline performance of the CIN and selecting realistic performance improvement metrics;
- (5) *Information Technology*-using electronic health records, patient registries or health information exchanges to measure performance objectively;
- (6) *Contracting Options*-creating a compliant and effective approach to negotiate with actors inside and outside the network; and
- (7) *Flow of Funds*-incentivizing members through transparent, understandable performance based compensation.

The increased quality of care, decreased costs and clearer, more efficient protocols resulting from a successful CIN can benefit patients, providers and hospitals. Patients within the CIN can potentially stay healthier, longer. Participating providers may experience increased demand through the CINs direct contracts, as well as increased revenue either from shared savings across the network or as a result of qualifying for incentive-based compensation. Similarly, participating hospitals can potentially achieve decreased length of stay, provide more appropriate care, lower readmission rates and work more closely with local providers without exposing the hospital to tainted assets or other liabilities of the doctor’s practice (as might be the case with an acquisition or merger).

While the benefits of clinical integration are clear, CINs also face legal issues that, if not properly addressed, will negatively impact their success. Among other things, clinical integration raises concerns with fraud and abuse statutes such

as the Physician Self-Referral (Stark) Law, the Anti-Kickback Statute and the Civil Monetary Penalties Law, as well as federal and state antitrust laws.

### **Physician Self-Referral (Stark) Law**

The Stark law forbids physicians from referring Medicare patients to entities for the furnishing of designated health services (DHS), if the physicians have a financial relationship with the entity and no exception applies. 42 U.S.C. § 1395nn. Because the Stark law is a “strict liability” statute, bad motives or intent is not required for the government to prove a violation occurred.

CINs implicate the Stark law when their contracts with participating physicians constitute “compensation arrangements” within the meaning of the Stark law. Importantly, a compensation arrangement may exist indirectly even if a clinical integration network neither furnishes DHS to Medicare beneficiaries nor bills such Federal health care programs for those services.

If Stark applies, the compensation relationship must satisfy an exception to avoid significant penalties, such as denial of payment by (as well as refunds to) Federal health care programs, plus fines, exclusion from participation in the Federal health care programs and penalties under the Civil Monetary Penalties Law (CMP). While the applicability of a Stark law exception to a particular clinical integration depends on how that clinical integration is structured, commonly used exceptions include:

- (1) Fair Market Value;
- (2) Risk Sharing Arrangements;
- (3) Indirect Compensation;
- (4) Personal Services;
- (5) Employment; and
- (6) Electronic Health Records Items and Services.

42 C.F.R. § 411.357. Determining whether any of these exceptions applies can be complicated for several reasons. First, physician compensation models commonly used by CINs—e.g., variable, performance-based compensation—are different from the more traditional “hours worked” model on which the Stark law is premised, creating greater risk of a violation. See Letter from American Hospital Association to the FTC,

DHHS and CMS (Sept. 27, 2010). Second, many of the exceptions listed above require compensation arrangements to be consistent with fair market value (“FMV”); however, there often is no generally accepted method of calculating FMV for CIN payments to physicians, such as performance-based incentive compensation or shares of cost savings. Therefore, those interested in clinical integration should consider retaining a valuator as well as legal counsel to achieve innovative compensation arrangements without violating Stark.

### **The Anti-Kickback Statute (the AKS)**

A criminal law, the AKS prohibits the knowing and willful payment of “remuneration” to induce or reward either the referral of patients or recommending or arranging for the ordering of goods or services that are reimbursable by a federal health care program, e.g., Medicare or Medicaid. 42 U.S.C. § 1320a-7b(b). As with the Stark law, CINs should ensure their compensation arrangements with participating providers comply with AKS, or else physicians may face fines, jail terms, and exclusion from Federal health care programs, as well as other penalties under the CMP.

Of particular concern with CINs is the risk that prosecutors will misconstrue the network’s compensation arrangements as a veiled attempt to induce physicians to refer to participating hospitals. This risk can be avoided by satisfying a voluntary safe harbor, such as:

- (1) Risk Sharing and Other Arrangements with Managed Care Organizations;
- (2) Personal Services and Management Contracts;
- (3) Employment; and
- (4) Electronic Health Records Items and Services.

42 C.F.R. § 1001.952. Satisfying these safe harbors can be a difficult task, however, since variable compensation agreements and other at-risk incentives are automatically excluded from the first safe harbor mentioned above, since such payments are, by definition, not “set in advance.”

### **The Civil Monetary Penalty (the CMP) Law**

The CMP law authorizes the imposition of substantial civil money penalties against any hospital that knowingly makes payments directly or indirectly to a physician involved in the

## **HLB Briefs**

**Hooper, Lundy & Bookman is pleased to announce that Eric Chan, Tracy Jessner Hale, and Vinay Kohli have been selected as 2017 Rising Stars in Southern California by SuperLawyers®.**

**SuperLawyers uses a combination of peer nominations, and independent research as selection criteria. Rising Stars must be 40 years old or younger, or have been practicing less than 10 years.**

direct care of a Medicare or Medicaid patient, for the purpose of inducing the physician to reduce or limit medically necessary services. 42 U.S.C. § 1320a-7a(b). For many years the CMP law was a formidable barrier to hospitals participating in the creation of any financial incentive for physicians to control health care costs, because the OIG interpreted the CMP law as prohibiting even financial incentives to reduce or eliminate wasteful or unnecessary care. A couple years ago, however, Congress added the words “medical necessity” to the wording of the CMP law, thus significantly easing the regulatory concerns presented by carefully tailored and closely monitored financial incentive programs designed to control costs by making care more efficient and effective, and eliminating waste.

## Antitrust

The antitrust laws are intended to regulate businesses in order to promote fair competition for the benefit of consumers. Certain activities constitute *per se* violations of the antitrust laws, such as price fixing, market allocation and group boycotts.

Notably, the Federal Trade Commission (FTC) has issued guidance and advisory opinions indicating that a CIN can jointly negotiate rates for competing providers without committing a *per se* violation of the bar against price fixing, so long as the CIN involves substantial clinical integration designed to improve quality and efficiency in service delivery. The FTC has not as yet specifically identified the amount of clinical integration necessary to permit joint price negotiations. However, a number of important characteristics of clinical integration have been identified, including the following:

- (1) development, implementation and enforcement of detailed, evidence-based clinical practice;
- (2) commitment by all participating physicians to the CIN's goals and requirements, despite associated restrictions on the physician's independent decision-making;
- (3) measurement and evaluation of each participating provider's compliance with the protocol;
- (4) sanctions for providers consistently failing to meet protocols, including potential exclusion from the network; and
- (5) investment by all participating providers of the time, energy and capital required to both develop and enforce clinical protocols and have access to the proper computer infrastructure to report compliance with protocols and facilitate the clinical integration.

If a CIN's successful clinical integration does not constitute a *per se* violation, courts apply the fact-intensive “rule of reason” test to determine whether the CIN complies with the antitrust laws. “A rule of reason analysis determines whether the formation and operation of the joint venture may have a substantial anticompetitive effect and, if so, whether the potential effect is outweighed by any procompetitive efficiencies resulting from the joint venture.” U.S. DOJ and FTC, *Statement 9A: Antitrust Enforcement Policy in Health Care* (U.S. DOJ and

FTC, Aug. 1996), available at [https://www.justice.gov/atr/statements-antitrust-enforcement-policy-health-care#CONTNUM\\_106](https://www.justice.gov/atr/statements-antitrust-enforcement-policy-health-care#CONTNUM_106) (visited June 28, 2017).

## Conclusion

At first blush, certain components to a successful clinical integration strategy may appear to conflict with key laws affecting the healthcare industry. Compensation arrangements tied to outcome-based financial incentives may risk violating fraud and abuse laws (Stark, the AKS and the CMP). Similarly, developing a joint contract negotiation strategy among otherwise competing providers risks an enforcement action by state and federal antitrust regulators. While CINs have been and continue to be successful when properly advised and structured, compliance with the fraud and abuse and antitrust laws is heavily fact-intensive. Accordingly, early retention of competent legal counsel can make all the difference.

*For additional information, please contact David Henninger, Charles Oppenheim or Kevin Royer in Los Angeles at 310.551.8111.*

## Bankrupt Lab Sues Physicians and Hospitals Nationwide

*by Charles Oppenheim*

The bankruptcy trustee for Health Diagnostic Laboratory, Inc. (HDL) is bringing actions in federal bankruptcy court in Richmond, Virginia, against over a thousand medical practices, clinics and hospitals (the Providers) all over the country, in an effort to recover alleged kickbacks paid to the Providers by HDL, in the form of processing and handling fees for specimens collected by the Providers and sent to HDL for testing.

HDL was investigated for these alleged kickbacks and entered into a \$47,000,000 settlement in April, 2015 with the U.S. Department of Justice for alleged False Claims Act violations, based on claims submitted to federal health care programs for lab tests performed by HDL as a result of referrals from providers who allegedly received kickbacks in exchange for their referrals. The negative publicity surrounding this investigation, and the resulting settlement, caused HDL's business to plummet. This collapse in business, together with the substantial settlement payment made by HDL, led to HDL filing for bankruptcy.

Now, the bankruptcy trustee has filed these actions against Providers around the country in an effort to claw back the processing and handling fees paid to the Providers by HDL. The bankruptcy trustee is asserting in court filings that the fees paid to Providers were kickbacks, and is proffering various legal theories under federal law, including bankruptcy law, and under various state law theories, to demand return of these amount from Providers. We are assisting a number of Providers to evaluate and respond to these lawsuits. Many Providers have not yet been served notice of the claims against

them, but will be receiving notice in the weeks to come.

Meanwhile, in separate actions, the Office of Inspector General of the Department of Health and Human Services (the OIG) is pursuing certain of the same Providers for alleged violations of the federal anti-kickback statute. The OIG has already settled some of these cases, and is actively pursuing settlements in others. The OIG's position is that the bank-

ruptcy actions are separate, and settling with the bankruptcy trustee does not limit a Provider's potential liability to the OIG. We are also assisting Providers with these issues.

*For more information, please contact: In Los Angeles, Charles Oppenheim at (310) 551-8110; in Boston, David Schumacher at (617) 532-2704.*

## CALENDAR

- May 5** Southern California Association for Risk Management, 37th Annual Education Conference; Rancho Mirage, CA  
Nina Marsden co-presented *Case Law and Legislative Update*
- June 1** CAMSS 46th Annual Educational Forum, Long Beach, CA  
Jennifer Hansen and Harry Schulman presented *Credentialing Strategies for All Provider Entities*; Katherine Dru presented. *The Ever-Expanding Roles of Allied Health Professionals*.
- June 7, 20, 21** California Hospital Association Hospital Finance & Reimbursement Seminar, Sacramento, Glendale, Costa Mesa, CA  
HLB attorneys were lead faculty for this seminar. Presenters included Lloyd Bookman (lead faculty member), John Hellow, and Robert Roth.
- June 28** American Health Lawyers Association Annual Meeting, San Francisco, CA  
David Schumacher was a panelist on *Health Care Fraud Enforcement Priorities*.
- July 11** California Hospital Association, Managing Patients With Behavioral Health Needs in Acute and ED Settings Seminar, Sacramento  
Steve Lipton presented *EMTALA and 5150s - A No Holds-Barred Review*
- July 16-19** California Association of Health Facilities Summer Conference, Long Beach, CA  
Mark Reagan participated on a panel addressing *Arbitration Agreement Best Practices*; Mark Johnson presented *Fraud & Abuse Update*.
- July 25** California Hospital Association, Managing Patients With Behavioral Health Needs in Acute and ED Settings Seminar, Pasadena  
Steve Lipton presented *EMTALA and 5150s - A No Holds-Barred Review*
- August 22, 24** Hooper, Lundy & Bookman, 2017 California Managed Care Update, Berkeley, Los Angeles  
This seminar for California health care providers addresses the potential impact of health reform, changing provider contracts and regulation on managed care providers. For additional information, please contact Daron Tooch at 310.551.8192.
- October 29 - November 1** HCCA's 3rd Annual Healthcare Enforcement Compliance Institute, Washington, D.C.  
Charles Oppenheim presents *Kickback and Stark Law Developments*.

# 2017 Hospital Compliance Manual Addresses Anti-Kickback Statutes and More

The California Hospital Association (CHA) has released the 2017 California Hospital Compliance Manual, its 8th edition.

The 2017 edition has been updated to address anti-kickback statutes for waivers of beneficiary copays and deductibles, IRS safe harbors for management contracts entered into by tax-exempt hospitals, new signage requirements regarding nondiscrimination, and more. CHA's Compliance Manual is the only publication written for hospital compliance officers that covers state and federal laws regarding high-risk compliance areas.

Written by attorneys from Hooper, Lundy & Bookman, PC and CHA, the Compliance Manual focuses on the key components of an effective compliance program. The thoroughly indexed manual features 700 pages and includes a model hospital compliance plan.

For more information and to order the new manual, visit [www.calhospital.org/compliance](http://www.calhospital.org/compliance).



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