February 6, 2017

TO: Users of CHA’s California Hospital Compliance Manual
FROM: Lois J. Richardson, Esq.
      Vice President and Counsel, Legal Publications and Education
SUBJECT: 2017 California Hospital Compliance Manual

CHA is pleased to publish the California Hospital Compliance Manual as a service to our members. The California Hospital Compliance Manual provides guidance to hospitals and health systems on how to comply with myriad California and federal statutes, regulations, agency guidelines and judicial decisions. The manual was written by attorneys with Hooper, Lundy & Bookman, PC, under the direction of Lloyd A. Bookman, Esq., and me.

This memorandum highlights some of the major changes in state and federal compliance-related laws, all of which are discussed in detail in this 2017 edition. This eighth edition reflects changes in the law through Dec. 31, 2016, unless otherwise noted.

It is suggested that you keep this memorandum with the manual for convenient reference. Because laws often change after publication, CHA advises hospitals to consult their attorney when a legal question arises.

**New Laws and Revisions**

The following is a summary of major changes:

- The manual has been updated throughout to reflect the higher CMPs now available for violations of federal laws.

- The intersection of compliance programs with the 60-day rule and the Office of Inspector General’s (OIG’s) permissive exclusion authority, including the OIG’s recently revised policy statement about compliance programs, has been described in the manual. *(Chapter 1)*

- The new requirement for skilled nursing facilities to have a compliance program is discussed. *(Chapter 1)*

- A federal court’s interpretation of the False Claims Act defense of good faith reliance on the advice of counsel is discussed. *(Chapter 2)*

- The U.S. Department of Health and Human Services has adopted a waiver of the anti-kickback statute and the Stark law for the Joint Replacement Model. *(Chapters 6 and 7)*
Notable Changes

New anti-kickback statute safe harbors have been enacted for drug discounts under the Medicare coverage gap discount program and free or discounted local transportation for patients. (Chapter 7)

The anti-kickback statute safe harbor for waivers of beneficiary copays and deductibles has been clarified. (Chapter 7)

A new state law requires certain outpatients to be notified if the service they seek is also available in another location that is not hospital-based. (Chapter 8)

The IRS private letter ruling regarding exempt status for commercial ACOs is discussed. (Chapter 9)

New IRS safe harbors for management contracts entered into by tax-exempt hospitals financed by tax-exempt bonds are explained in detail. (Chapter 9)

California law now allows hospitals to have specific observation units. (Chapter 10)

Information about the effect of a change in ownership on the quality assurance fee has been added. (Chapter 10)

Information about the interpretation of Section 603 of the Bipartisan Budget Act of 2015, which prohibits certain new off-campus outpatient departments from receiving reimbursement under OPPS, has been added. (Chapter 10)

A discussion of guidance from the U. S. Department of Health and Human Services and significant legal decisions about patient safety organizations has been added. (Chapter 13)

A discussion of laws about handling driver’s license information, and information collected when accepting payment by check or credit card has been added. (Chapter 14)

The required hospital signage chart has been updated to include revised requirements for skilled nursing facility complaint and advocacy group information, grievance information, and survey results under the Conditions of Participation; new requirements regarding nondiscrimination, accessibility and language assistance services under Section 1557 of the ACA; and observation units under state law. (Chapter 12)

In addition, the eighth edition of the manual contains many minor changes in the law, changes in websites, additional resources, compliance tips, and clarifications that are too numerous to list.

To order additional manuals, visit the CHA website at www.calhospital.org/publications. CHA publishes a variety of hospital compliance manuals including manuals on consent law, EMTALA, licensing and certification surveys, health information privacy, mental health law, records retention requirements and more.

CHA members with questions regarding this memorandum or the content of the California Hospital Compliance Manual may contact me at (916) 552-7611 or lrichardson@calhospital.org.

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