CALIFORNIA ASSOCIATION of PUBLIC HOSPITALS AND HEALTH SYSTEMS

August 29, 2018
The Honorable Ed Hernandez, O.D.
State Capitol, Room 2080
Sacramento, CA 95814

Subject: Concerns – SB 1447 (Hernandez) Automated Drug Delivery Systems Licensure

Dear Senator Hernandez,

On behalf of the members of the California Association of Public Hospitals and Health Systems (CAPH) and the millions of patients they serve, I am writing you at this late moment in time to describe our concerns with your bill, SB 1447, and to hopefully memorialize them for consideration by the Legislature next year. We very much appreciate the time and effort spent by your office working with CAPH to more fully understand and appreciate the unique circumstances of public health care systems, and their uses of Automated Unit Dose Systems (AUDS). Frankly, we held off taking a position on your bill for many months in the hopes that we could reach an agreement following numerous conversations with the Board of Pharmacy and your office on amendments. Unfortunately, this was not achieved. CAPH plans to continue a dialogue with the Board of Pharmacy, in hopes of helping them to better understand the unique structure of public health care systems, and their clinics, and how that could translate into a more simplified and efficient oversight of AUDS used throughout their systems. Through these conversations, we hope that the Board of Pharmacy will be able to come away with the information necessary to understand where public health care system AUDS are located, and how they are operated.

CAPH remains concerned that several provisions in SB 1447 may, in fact, impede patient care and prevent public health care systems from using improved and updated pharmaceutical practices. CAPH also wants to clearly state that our focus has, and continues to be on AUDS, used by *providers* to administer medications to patients while they are under medical supervision; we do not take any issue with the provisions regarding Automated Patient Dispensing Systems (APDS), which are those accessed directly by *patients* to fill take home prescriptions. CAPH believes that the differences between these two types of Automated Drug Delivery Systems (ADDS) lend themselves to different oversight.

CAPH also asserts that public health care systems, which are composed of both hospital facilities and a unique array of (hospital and non-hospital based) clinics, but nevertheless part of the same public health care system, lend themselves to a modified type of oversight and licensure by the Board of Pharmacy as they function as one legal entity, which is recognized in statute.

CAPH has a longstanding relationship with you and we appreciate all of your efforts to improve patient care. CAPH felt that it was important to put public health care systems' concerns in writing, which are detailed below in this letter. We remain concerned about the implementation date of July 1, 2019, and

question whether it will allow sufficient time for public health care systems to adhere to the new regulations, and ensure that the Board of Pharmacy can approve all of these new licenses in a timely manner. Should this bill become law, CAPH fully intends to work with public health care systems to comply with these new requirements, and we remain committed to working with the Board of Pharmacy and the Legislature to address implementation issues as they arise.

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California's 21 public health care systems are the core of the state's health care safety net, delivering high quality care to all who need it, regardless of ability to pay or insurance status. Most patients seen in public health care systems are either Medi-Cal beneficiaries or are uninsured. Public health care systems provide services to more than 2.85 million Californians annually, provide nearly 30 and 40 percent of the hospital care to the state's Medi-Cal and uninsured populations, respectively, and provide 11.5 million outpatient visits each year. Public health care systems also operate half of the state's top-level trauma and burn centers, and train 57% of all new doctors in the state.

ADDS Background

SB 1447 repeals and replaces the current ADDS definition and establishes it as a new umbrella term, including both AUDS, also commonly referred to by health care professionals by the manufacturer's name such as Pyxis or Omnicell, and APDS. As stated earlier, AUDS are used by providers in a health facility setting to store and administer medications to patients while they are under medical supervision. On the other hand, APDS are sophisticated prescription drug vending machines that are accessed directly by patients to dispense take home prescriptions. The bill exempts AUDS located within acute hospitals and acute psychiatric hospital facilities, but requires *all* other ADDS to maintain a separate license. The bill also includes a number of other new requirements surrounding stocking procedures, ADDS technological capabilities, staff training, and compliance.

Throughout our discussions with the Board of Pharmacy, it was evident that the primary concern the bill sought to address related to APDS, which, as previously stated, are directly accessed by patients to fill take home prescriptions. CAPH did not raise any concerns with the new requirements for APDS, all of our suggested amendments related to AUDS.

Benefit of AUDS in Care Delivery

AUDS are only operated by providers and are important in making sure public health care systems can appropriately administer drugs to patients. In addition to being more efficient, these machines have a number of security measures in place such as biosensors, contraindication safeguards, and medication tracking capabilities, which make them safer options for medication delivery than traditional methods by reducing medication errors. In addition, they are effective in improving overall compliance, and assist in minimizing drug theft. AUDS help prevent providers from administering the wrong dose or medication to patients, and help streamline safer drug administration. AUDS also establish consistent oversight of

what has been prescribed, and administered, by providing a clear record of all drugs accessed from the machine, including which provider removed the medication and the patient that received it.

Overview of SB 1447 Concerns

CAPH has identified a number of concerns in SB 1447, which, if enacted into law, may be problematic for public health care systems to continue delivering effective and efficient patient-centered care:

1. Each AUDS must have its own license that is renewed annually. Although SB 1447 exempts hospital facilities from the AUDS licensing requirements, non-hospital clinics and other facilities would be required to obtain a license for *each* AUDS they operate. All AUDS licenses must also be renewed annually. Furthermore, providers would be required to apply for a *new* license every time they needed to move an AUDS to either a different room within the same clinic, or to a new location. Several public health care systems operate hundreds of AUDS throughout their primary and specialty care clinics; our systems need flexibility in where AUDS are located so that they can respond to emergencies such as flu outbreaks, or serve hard to reach populations such as by offering local immunization drives. Having to annually license each AUDS, and apply for a new license every time one is moved, in facilities that are already licensed to provide pharmacy services by the Board of Pharmacy, is burdensome and not conducive to how public health care systems provide patient centered care and respond to emergencies.

2. CAPH is concerned that the Board of Pharmacy will not have sufficient time to process and approve these license applications in a timely manner, before the July 1, 2019, implementation date. While SB 1447 requires the Board of Pharmacy to conduct a pre-licensure inspection within 30 days of receiving an AUDS application, there is no time requirement for the license to be issued. Requiring, likely thousands, of these AUDS (not including the effort it will take for APDS) across the state to secure new licenses before July 1, 2019, could result in greater public health care system inefficiencies as systems will have to either limit where they provide medication services, stop using AUDS until the Board of Pharmacy issues each AUDS its own license, risk being out of compliance, or deploy a combination of these actions.

3. SB 1447 limits the types of facilities that AUDS may be located. A number of other types of health facilities that offer essential community services such as behavioral health, substance use disorder treatment, and services for homeless persons may also be prohibited from using AUDS under SB 1447. This could disrupt access and availability of treatment options, or revert medication delivery back to older methods that are less efficient and have fewer tracking and safety measures. For example, providers could resort to storing provider administered medications in a locked cabinet with a notebook for logging inventory; this could result in greater drug theft or problems with compliance, which is contrary to one of the main issues the Board of Pharmacy seeks to address through SB 1447. The requirements in SB 1447 need to

adequately reflect all of the different venues that patients receive health care services so that public health care systems can continue to deliver care in the most appropriate setting.

After significant effort was made to explain public health care systems' concerns and propose multiple solutions to both the Board of Pharmacy and your office, we were disappointed that only the exemption for hospital facilities was incorporated into SB 1447. Public health care systems, often with expansive networks of clinics, look quite different from the private sector; therefore, we are particularly challenged by many of the requirements of this bill. We remain especially concerned about the implementation deadline and the Board of Pharmacy's ability to approve licenses in such a short timeframe. Although we will make every effort to support public health care systems in meeting these new requirements, SB 1447 makes significant changes to the governance of pharmaceutical delivery, and its timeline for coming into compliance is especially challenging.

Should this legislation be signed into law, we hope that our concerns will be taken into consideration and addressed during the next legislative session. We understand that the Board of Pharmacy is committed to continuing to work with CAPH on these issues and we hope that they will honor this commitment next year.

We would be pleased to further discuss our position with you and answer any questions you may have. Please contact Terri Thomas, our Sacramento representative, at 916-325-1010 if you would like to follow-up. Thank you for your consideration.

Sincerely,

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