

## **SUPPLEMENTAL STATEMENT OF REASON**

The California Department of Public Health (the “Department”) has instituted additional changes to these proposed regulations, and they are discussed below. These changes are either initiated by the Department or are in response to comments that were received during the 45-day public comment period that ended on December 8th, 2018.

### **Section 79900**

#### **Subparagraph (b)**

In response to a public comment, the Department has changed the terms “health facility” and “facility” to “health care facility.” This change was made throughout the proposed regulations text as well. This change ensures internal consistency through the regulation text. This change also adds specificity as to which facilities are subject to the proposed regulations.

### **Section 79901**

#### **Subparagraph (c)(1)**

In response to a public comment, the Department has added the phrase “on behalf of the health care facility or health care system” in definition of the term “business associate” in subparagraph (c)(1). The Department made this change to bring this definition into conformity with the parallel definition utilized in the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This change is made to ensure consistency between these regulations and federal law.

#### **Subparagraph (m)**

In response to a public comment, the Department has made the term “patient representative” a defined term. The Department, has defined the term “patient representative” as used in these regulations to have the same meaning as patient representative as defined in Health and Safety Code section 123105, subdivision (e). This addition will remove any lack of clarity caused by not defining the term previously in regulations text. In addition, this amendment will ensure there is consistency between these regulations and statutory definitions.

#### **Subparagraphs (n),(o),(p)(q)**

As a result of the addition made above in section 79901(n), these sections have been relettered to maintain the numbering scheme.

### **Section 79902**

#### **Subparagraph (a)**

In response to a public comment, the Department has made a deletion to the regulation text to clarify when a health care facility is required to report breaches reasonably believed to have occurred. The Department has struck the word “suspected” from section 79902, subparagraph (a) line 1 between “or a” and “breach.” This change is intended to address a lack of clarity in the previous version of the regulation text.

In response to a public comment, The Department has made an addition to the text to clarify who is responsible for reporting breaches to the Department. The Department has inserted the phrase “excluding a business associate” in section 79902, subparagraph (a) line 1 between “[a] health care facility” and “shall report.” This change is intended to address a lack of clarity in the previous version of the regulation text that could be interpreted as requiring a “business associate” to report a medical information breach to the Department. The Department makes this change to clarify that health care facilities shall report medical information breaches to the Department on behalf of their business associates.

**Subparagraph (a)(1)(I)**

In response to a public comment, the Department has adopted language to ensure the term “health care facility” is used consistently throughout the regulation text. The Department has inserted the words “health care” before “facility” in the first sentence of section 79902, subparagraph (a)(1)(i). This global change is discussed more fully described above in the comment to section 79900 (b) above.

**Subparagraph (a)(1)(K)**

In response to a public comment, the Department has adopted language to limit the period of time that a health care facility must submit records related to a reported event that includes a breach of a patient’s medical information. The department has inserted the words “in the six years prior to the event” at the end of the sentence. This change is made to bring these regulations into conformance with HIPAA requirements related to the inspection of records.

**Subparagraph (a)(1)(M)**

In response to a public comment, the Department has adopted language to ensure the term “health care facility” is used consistently throughout the regulation text. The Department has inserted the words “health care” before “facility” in the first sentence of section 79902, subparagraph (a)(1)(M). This global change is described above in the comment regarding section 79900, subparagraph (b).

**Section 79904**

**Subparagraph (a)(3)**

In response to a public comment, the Department has adopted language to ensure the term “health care facility” is used consistently throughout the regulation text. The Department has inserted the words “health care” before “facility” in the first sentence of section 79904, subparagraph (a)(3). This global change is described above in the comment regarding section 79900, subparagraph (b).

**Section 79905**

**Subparagraph (c)**

In response to a public comment, the Department has adopted language to ensure the term “health care facility” is used consistently throughout the regulation text. The Department has inserted the words “health care” before “facility” in the first sentence of section 79905, subparagraph (c). This global change is described above in the comment regarding section 79900, subparagraph (b).