

## **Ultrasound Quality Assurance and Safety Act**

*Summary: The Ultrasound Quality Assurance and Safety Act requires that an ultrasound device can only be used by a licensed medical professional operating within their scope of practice.*

Based on [WA SB 6151 \(2024\)](#)

### **SECTION 1. SHORT TITLE**

This Act shall be called the “Ultrasound Quality Assurance and Safety Act.”

### **SECTION 2. FINDINGS**

The legislature finds that:

1. An ultrasound machine is a medical device that uses high-frequency sound waves to create images of the inside of the body.
2. The U.S. Food and Drug Administration, which is responsible for approving all prescription drugs and medical devices for human use, considers the use of ultrasound energy on humans to be the practice of medicine and must be done for clear medical indications and be performed by trained and licensed medical providers. The FDA opposes the use of ultrasound machines by anyone other than appropriately trained and licensed medical professionals, under the supervision and authority of a licensed physician.<sup>49</sup>
3. The American Institute of Ultrasound in Medicine (AIUM) official statements<sup>50</sup> on the use and safety of ultrasound in pregnancy strongly discourage the use of ultrasounds for any non-medical purpose, advise that diagnostic ultrasound in pregnancy should only be performed when there is a valid medical indication, and recommend that all fetal ultrasound examinations be performed by appropriately trained and credentialed medical professionals who have received specialized training in fetal imaging and meet the AIUM training guidelines.<sup>51</sup> The AIUM also emphasizes that all pregnancy ultrasound imaging requires proper documentation and a final report for the patient's medical record signed by a physician or an advanced clinical provider legally responsible for interpretation.<sup>52</sup>
4. Nevertheless, ultrasound machines are being operated by untrained staff and volunteers in a number of circumstances. These include: “elective” standalone ultrasound “centers,” which may or may not have appropriately trained and supervised staff;<sup>53</sup> “keepsake” ultrasound photo studios to take pictures for framing;<sup>54</sup> and Unregulated Pregnancy Clinics (UPCs) [or use another name if it's common for your state] that often offer “non-diagnostic” ultrasound imaging.

5. It is therefore necessary and appropriate for state law to specify under what conditions an ultrasound can be performed.

### **SECTION 3. QUALITY ASSURANCE FOR ULTRASOUND**

After section XXX, the following new section XXX shall be inserted:

#### **(A) OPERATION OF ULTRASOUND LIMITED TO LICENSED PROFESSIONALS**

1. An ultrasound or a similar medical imaging device or procedure may only be used on a person by:

(a) A health care provider holding an active license under (cite appropriate code sections) and acting within their scope of practice; or

(b) A person acting under the direct supervision of a health care provider holding an active license under (cite appropriate code sections), where all actions performed are within the supervising health care provider's scope of practice.

2. This section does not apply to the practice of a licensed midwife providing care pursuant to (cite code) or the practice of a certified nurse-midwife providing care pursuant to (cite code). [If other medical exemptions should apply based on the licensing system in your state, they would go here.]

3. [OPTIONAL PROVISION, but note that the CA and WA laws have no exceptions for non-medical uses.] This section does not apply if the ultrasound is performed for the sole purpose of creating keepsake photos or videos.

#### **(B) ENFORCEMENT**

1. Whenever the Attorney General or a district attorney [if applicable: a city attorney, a county counsel] has reasonable cause to believe that a person, partnership, or corporation has violated this section, the Attorney General may issue a civil investigative demand pursuant to [cite code].

2. The Attorney General may commence an action in any court of competent jurisdiction for injunctive relief to compel compliance with the provisions of this section, and for civil penalties for violations.

3. Prior to commencing an action in court, the Attorney General shall give written notice to the person, partnership, or corporation to cure such violations not later than 10 business days after receipt of the written notice.

4. Upon a finding by the court that a person, partnership, or corporation has violated this section, the state shall be entitled to recover:

- (a) civil penalties of up to three thousand dollars for a first violation;
- (b) civil penalties of up to ten thousand dollars for a second or subsequent violation; and
- (c) reasonable attorneys' fees and costs.

5. In determining the overall amount of civil penalties to assess against a person, partnership, or corporation, the court shall include, but not be limited to the following in its consideration:

- (a) the nature and severity of the violation;
- (b) the size, scope, and type of the offending organization; and
- (c) the good faith cooperation of the offending organization with any investigations conducted by the Attorney General pursuant to this section.

#### **SECTION 4. EFFECTIVE DATE**

This law shall become effective on July 1, 20XX.