# Examples of Software That Would Be Deregulated Under the PROTECT Act

In making this list of examples of software that the PROTECT Act would remove from FDA regulation, we have broken the list down into two different buckets: (1) high risk CDS and (2) mobile medical apps and other medical device functionality. In looking at this list, it's important to understand that the items on this list are presently regulated by FDA, and have been so since they were first marketed in some cases many years ago.

## High Risk CDS

Many of the following examples flow from one simple principle. A good indicator of risk for CDS is when the user is substantially dependent on the software for clinical decision-making. Those situations can arise in many different contexts, but generally involve a serious or life-threatening disease or condition.

The following list is illustrative of types of software that are (1) CDS and (2) would become no longer regulated by FDA under the PROTECT Act.

1. Apps and other software that guide untrained users to make very complex medical decisions.
    a. Example 1: Consumer Use Melanoma Apps. There are software apps being introduced that claim to allow ordinary consumers to spot moles that are potentially cancerous. With one of these apps, a consumer might take a picture of a mole on her skin with her cell phone camera, and then take a picture again in six months, and the app is supposed to say whether the mole has changed in a way that could suggest melanoma, in which case the app would recommend the consumer go to the doctor. But what happens if the app misses a potential melanoma?
    b. Example 2: Sports Concussion Injury Apps. There are mobile apps that use the built-in motion sensors of a mobile device to analyze postural sway, a key factor in assessing, managing, and monitoring concussion symptoms and orthopedic dysfunction. These apps can be used by football coaches to assess whether a player has been hurt such that he needs to be taken out of the game and seen by a doctor. But what happens if the app suggests a player is fine when he is not?
    c. Example 3: Drug dose calculators. Long used by physicians to help them calculate drug dose, more recently physicians are recommending that patients get drug dosage calculators configured to a particular drug. For example, for a person with diabetes, the calculator will allow them to calculate the proper amount of insulin to take considering all of the various factors such as blood glucose level.
    d. Example 4: Disease managers for patients. A diabetes manager guides a person with diabetes to manage the various factors that influence the disease. Based on patient input this software recommends course of action for the patient to take , including

drugs or food or drink, and based on longitudinal analysis provided by the system, the app recommends to primary care physicians how to titrate medications for diabetics.

2. Software used in a setting that does not allow the doctor sufficient time to second-guess the software.
    a. Example 5: Emergency Care Predictive Analytics Software. Emergency room physicians and first responders are rushed to quickly consider all the facts and make first a diagnosis and then a therapeutic decision. More and more we are exploring ways to assist these physicians and EMTs operating under extreme pressure to consider all of the relevant information as they reach a decision. This category of software may process and analyze large amounts of both structured and unstructured healthcare data and vital sign data to recommend and adjust a treatment in an emergency care setting. Specifically, the software analyzes the information using a multi-factorial algorithm and issues treatment recommendation, which may include medication dose values and instructions. Considering the volume of information that the software considers and the little time available to the doctor or EMT, there is no practical way for the physician or EMT to read, understand and critically evaluate the basis for the computer's recommendation. But what happens if the software gets it wrong, and rather than follow his own instincts, the doctor/EMT goes along, nervous that the computer has thought of something that he hasn't?
    b. Example 6: Hospital patient monitoring software. For years, hospitals have struggled with how to help nurses be vigilant in watching the patients under their care. In the early days, many vendors of specific monitors included alarms to alert nurses to a critical level. The problem is, those alarms are generally over inclusive, going off so often that nurses no longer treat them as truly indicative of an emergency. So now there is an emerging category of software using sophisticated analytics to assess the various data related to a monitored patient, giving nurses a more meaningful notification when a patient's health is deteriorating. As nurses and other caregivers become more dependent on these higher level analytics, what happens when one doesn't work, a patient crashes and the caregiver is alerted too late?
3. Software that takes a very complicated calculation and presents a result without transparently revealing the basis for the calculation.
    a. Example 7: Radiation dose calculator. Radiation treatment planning is generally performed on dedicated computers using specialized treatment planning software. Depending on the radiation delivery method, several angles or sources may be used to sum to the total necessary dose. The planner will try to design a plan that delivers a uniform prescription dose to the tumor and minimizes dose to surrounding healthy tissues. Many factors are considered by radiation oncologists when selecting a dose, including whether the patient is receiving chemotherapy, patient comorbidities, whether radiation therapy is being administered before or after surgery, and the degree of success of surgery.
    b. Example 8: Burn Victim Fluids Assessment. The software could, for example, use an advanced algorithm that learns how each patient responds to fluid therapy each hour.

The algorithm could use fluid in and out trend data to predict the fluid rate for the next hour that will best achieve the urine output target range.

These are just meant to be a few examples, but it isn't hard to imagine many others in each of the categories. For example, one can imagine software being devised to help patients make decisions about any number of diseases and whether they ought to visit their doctor or take a specific action. Further, the practice of medicine is getting ever more complicated and requires examination of huge amounts of data. Software offers an obvious ray of hope, but what happens when software ends up making very complex decisions and the physicians, either because time does not permit or because the software does not reveal enough to be evaluated, end up deferring to the software?

PROTECT Act Language Limiting the Act's Scope

Although the act does not define the term "clinical decision support" software, all of these examples would seem to meet the vernacular definition of such software. Thus, those examples that are for professional use would constitute "clinical software" and those that are not would constitute "health software."

Further, these software apps are not removed from the clinical and/or health software categories by virtue of subsection (ss)(3) on page 5 of the introduced legislation. The following language in the act does not keep these products regulated by FDA.

1. "that is intended to interpret patient-specific device data and directly diagnose a patient or user without the intervention of a health care provider"
    a. We are honestly not sure what this means, but it does suggest that software that counsels consumers on when to consult a physician would not be FDA regulated. In the examples above, this includes the melanoma app and the concussion app. Makers of such apps would undoubtedly argue that their software is not diagnosing the disease or condition, but simply helping to determining when a consumer should get a physician involved.
    b. Further, the language is focused solely on diagnosis, and therefore obviously does not apply to software that simply determines the appropriate treatment for a disease or condition, such as drug dosage calculators or disease managers.
2. "that conducts analysis of radiological or imaging data in order to provide patient-specific diagnostic and treatment advice to a health care provider"
    a. Again, we are not sure what "imaging data" refers to, and whether that includes a simple photograph taken with the camera phone, but in any event, this is limited to professional applications that guide healthcare providers. So obviously the melanoma example above that aids a consumer would not be FDA regulated.
    b. While not CDS, this category obviously would not exclude apps currently regulated by FDA that are used for the display of medical images, if that display does not also involve analysis, as discussed on the next section.

3. "whose primary purpose is integral to the function of a drug or device"
    a. We are not sure what the phrase "integral to the function of the drug" means, but it is not clear from that description that a drug dosage calculator would remain FDA regulated. Does integral mean that the drug cannot be used without the software? If so, most drugs can in fact be used without a calculator. Calculators aid the proper use of the drug, but would probably not be considered "integral."
    b. Indeed, there are many other areas of technology apart from these CDS categories that may or may not be integral to the functioning of a medical device and those technologies will have to be debated if this legislation is enacted. For example, as discussed in the next section, one common use of software now on standalone computers and mobile platforms is intended for the management and display of medical information like radiological images. So the question is, is an app that allows for the display of an ultrasound image on a mobile phone integral to the ultrasound machine that made the image? There are many different ways to display an image and it's an open question as to whether all of these ways of displaying an image are somehow "integral", and therefore regulated.
4. By these descriptions, none of the examples listed would qualify as components of a medical device. They are not unique or tailored to be used with any particular medical device.

## Mobile Medical Apps and Other Medical Device Functionality

The following are simply a few of the categories of currently regulated medical devices that would meet the new definitions of either clinical software or health software.

1. Professional use software that "captures, analyzes, changes, or presents patient … clinical data or information" (A/K/A "clinical software"). The term "clinical data or information" is not defined, so it would seem to easily include such things as medical images and laboratory values.
    a. Classifications for Medical Image Management Devices. The following five classifications for medical image management devices are currently provided in 21 CFR Part 892:
        i. Sec. 892.2010 Medical image storage device.
            1. Identification. A medical image storage device is a device that provides electronic storage and retrieval functions for medical images. Examples include devices employing magnetic and optical discs, magnetic tape, and digital memory.
            2. Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to Sec. 892.9.
        ii. Sec. 892.2020 Medical image communications device.
            1. Identification. A medical image communications device provides electronic transfer of medical image data between medical devices. It

may include a physical communications medium, modems, interfaces, and a communications protocol.

2. Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to Sec. 892.9.

iii. Sec. 892.2030 Medical image digitizer.

1. Identification. A medical image digitizer is a device intended to convert an analog medical image into a digital format. Examples include systems employing video frame grabbers, and scanners which use lasers or charge-coupled devices.
2. Classification. Class II (special controls; voluntary standards—Digital Imaging and Communications in Medicine (DICOM) Standard, Joint Photographic Experts Group (JPEG) Standard).

iv. Sec. 892.2040 Medical image hardcopy device.

1. Identification. A medical image hardcopy device is a device that produces a visible printed record of a medical image and associated identification information. Examples include multiformat cameras and laser printers.
2. Classification. Class II (special controls; voluntary standards—Digital Imaging and Communications in Medicine (DICOM) Standard, Joint Photographic Experts Group (JPEG) Standard, Society of Motion Picture and Television Engineers (SMPTE) Test Pattern).

v. Sec. 892.2050 Picture archiving and communications system.

1. Identification. A picture archiving and communications system is a device that provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. Its hardware components may include workstations, digitizers, communications devices, computers, video monitors, magnetic, optical disk, or other digital data storage devices, and hardcopy devices. The software components may provide functions for performing operations related to image manipulation, enhancement, compression, or quantification.
2. Classification. Class II (special controls; voluntary standards—Digital Imaging and Communications in Medicine (DICOM) Standard, Joint Photographic Experts Group (JPEG) Standard, Society of Motion Picture and Television Engineers (SMPTE) Test Pattern).

b. Medical device data systems. § 880.6310

i. Identification. A medical device data system (MDDS) is a device that is intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices:

1. The electronic transfer of medical device data;
2. The electronic storage of medical device data;

3. The electronic conversion of medical device data from one format to another format in accordance with a preset specification; or
4. The electronic display of medical device data.

ii. An MDDS may include software, electronic or electrical hardware such as a physical communications medium (including wireless hardware), modems, interfaces, and a communications protocol. This identification does not include devices intended to be used in connection with active patient monitoring.

iii. Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

c. Sec. 862.2100 Calculator/data processing module for clinical use.

i. Identification. A calculator/data processing module for clinical use is an electronic device intended to store, retrieve, and process laboratory data.

ii. Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in 862.9.

2. Data capturing functions. The proposed legislation specifically says that software used to "capture" "clinical information" would be clinical software. The only real limitation to that portion of the legislation is that the software cannot be integral to a medical device or a component of a medical device. Presumably those limitations mean that software that would reside inside of an x-ray machine or inside of a regulated laboratory instrument would not qualify as clinical software. But notice there is a bit of ambiguity even there because it begs the question of whether an instrument intended to capture clinical information is a medical device to begin with. Let's set that ambiguity aside, though, and look at how the legislation treats specialized medical software that resides on general purpose hardware intended to capture clinical information. A straightforward reading of the legislation would say that this is clinical software if used by healthcare professional and health software if used by a consumer, neither regulated by FDA. What would be examples of that?

a. An app that uses a regular cell phone and the built-in camera to conduct laboratory testing, for example urinalysis
b. Cell phone apps that use the cell phone speaker to conduct hearing tests.
c. Cell phone apps that use the cell phone screen to conduct eye examinations
d. Cell phone apps that use the cell phone microphone to operate as an electronic stethoscope
e. cell phone apps that use common and unregulated accessories like a heart rate monitor to manage heart conditions
f. Indeed any software intended for an unregulated product such as general-purpose laboratory equipment can be used for just about any medical purpose