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CDS Coalition

CDS Use Cases

The goal of this document is to put together a list of example CDS use cases, together with the appropriate regulatory status for each, to evaluate FDA and congressional proposals to determine if they achieve appropriate results. Of course, any policy proposal from FDA or Congress needs to be written broadly enough to anticipate future new use cases, but this document can be a starting point to evaluate federal policy initiatives.

FDA should not regulate software on which the user is not substantially dependent. To avoid making the user substantially dependent, the software must:

1. Be transparent in design, give the user both the underlying data and the clinical logic so that the user can assess for herself the correctness of the recommendation
2. Target people who are capable of making the required decision, and
3. Be aimed at care settings where the user will have sufficient time to make those decisions.

That is the baseline for regulation. FDA should not regulate software which does not create substantial dependence.

If software does create substantial dependence in the user, there are a variety of other factors that determine whether FDA should regulate the software and, if so, in what class. This paper will focus on those software programs. To bring some structure to this discussion, we organize the use cases according to some common categories. Obviously, one software program could include functionality from more than one category below.

CDS Software Category	Discussion	Unreg. or ED	Class I	Class II	Class III
I. Data input = an image					
a. Radiological image analysis: computer aided detection/diagnosis					
i. Oncology CAD. The software is used by radiologists, and processes digitized film in order to mark suspicious areas for review	FDASIA report[1]			x	
ii. Stroke CAD. Software that performs diagnostic image	IMDRF Risk Document[2]			x	

[1] FDASIA Health IT Report, Proposed Strategy and Recommendations for a Risk-Based Framework, dated April 2014 by the FDA, FCC and ONC at http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf

[2] "Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations, written by the International Medical Device Regulators Forum, published on September 18, 2014 at

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analysis for making treatment decisions in patients with acute stroke, i.e., where fast and accurate differentiation between ischemic and hemorrhagic stroke is crucial to choose early initialization of brain-saving intravenous thrombolytic therapy or interventional revascularization.					
iii. Software that interpolates data to provide 3D reconstruction of a patient's computer tomography scan image, to aid in the placement of catheters by visualization of the interior of the bronchial tree; in lung tissue; and placement of markers into soft lung tissue to guide radiosurgery and thoracic surgery.	IMDRF Risk Document		x		
iv. Differentiation between benign and malignant breast cancer nodules, based on multiple ultrasonographic features				x	
v. Computer-assisted texture analysis of ultrasound images aids monitoring of tumor response to chemotherapy				x	
b. Photographic image analysis – consumer					
i. Consumer melanoma app. This software allows consumers to use the camera on their smartphones to take a picture of a skin lesion or more. The app stores the pictures but also uses an algorithm based on the ABCD E method of detection to diagnose melanoma without the engagement of a healthcare professional.				x	
ii. App that explains how to check for Retinoblastoma using a		x			

http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf

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photograph of the eyes. The app explains how to do this manually, with photos as examples. The consumer analyses the photo; the software only educates.					
c. Photographic image analysis – professional					
i. Professional melanoma app. The app makes recommendations to the doctor based on complex algorithms applied to photographs including such modalities as fractal geometry.	IMDRF Risk Document			x	
ii. Software intended for image analysis of body fluid preparations or digital slides to perform cell counts and morphology reviews.	IMDRF Risk Document	x			
iii. Analysis of digital images of tissue sections to identify and quantify senile plagues for diagnosing and evaluating the severity of Alzheimer's disease				x	
d. Other types of images such as spectroscopy data					
i. Software that performs analysis of cerebrospinal fluid spectroscopy data to diagnose tuberculosis meningitis or viral meningitis in children.	IMDRF Risk Document			x	
ii. Early detection of prostate cancer based on serum protein patterns detected by surface enhanced laser description ionization time-of-flight mass spectrometry (SELDI-TOF MS)				x	
iii. Identification of breast cancer subtypes distinguished by pervasive differences in their gene expression patterns				x	
iv. Classification of electromyographic (EMG) signals, based on the shapes and firing rates of motor unit action				x	

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potentials (MUAPs)					
v. Predicting the presence of brain neoplasm with magnetic resonance spectroscopy				x	

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II. Data input = alpha-numeric data from devices					
a. Medical device data analysis software (we omit any software that takes data from a singular medical device because such software is likely to be an accessory, rather than CDS)					
i. Robotic surgical planning and control software that guides medical device input rather than analyzes medical device output. This may or may not be an accessory depending on how closely it is tied to a particular medical device.	FDASIA report			x	
ii. Software that analyzes heart rate data intended for a clinician as an aid in diagnosis of arrhythmia.	IMDRF Risk Document		x		
iii. Remote display or notification of real-time alarms (physiological, technical, advisory) from bedside monitors. Sometimes the software can be an accessory to a particular medical device, and sometimes it is more generic and therefore potentially CDS.	FDASIA report		x	x	
iv. Software indicated for aggregating, displaying on a real-time basis, and managing physiologic and other patient information in an ICU or emergency department setting. This information is generated by third party medical devices and patient information systems. The software performs automated calculations on patient data collected by third party devices based on approved clinical protocols at patient care facilities.				x	
v. Software that analyzes movement of the eye or other	IMDRF Risk Document	x			

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information to guide next diagnostic action of astigmatism. This may sometimes be an accessory, and sometimes if it focuses solely on an image might fit better in a different category.					
vi. Software intended for use by elderly patients with multiple chronic conditions that receives data from wearable health sensors, transmits data to the monitoring server, and identifies higher-level information such as tachycardia and signs of respiratory infections based on established medical knowledge and communicates this information to caregivers.	IMDRF Risk Document	x			
vii. Software that collects data from peak-flow meter and symptom diaries to provide information to anticipate an occurrence of an asthma episode. This software is very close to the line of constituting an accessory.	IMDRF Risk Document	x			
b. Analysis of data from laboratory instruments					
i. Classification of immature and mature white blood cells (neutrophils series) using morphometrical parameters ISPAHAN			x		
ii. Software that combines data from immunoassays to screen for mutable pathogens/pandemic outbreak that can be highly communicable through direct contact or other means.	IMDRF Risk Document			x	
iii. Identification of novel patterns in high-dimensional metabolic data for the construction of			x		

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classification system to aid the diagnosis of inherited metabolic diseases					
iv. Software that integrates and analyzes multiple tests utilizing standardized rules to provide recommendations for diagnosis in certain clinical indications, e.g., kidney function, cardiac risk, iron and anemia assessment.	IMDRF Risk Document		x	x	
c. Analysis of data from nonmedical devices					
i. Software that uses hearing sensitivity, speech in noise, and answers to a questionnaire about common listening situations to self-assess for hearing loss.		x			
ii. Software that analyzes data from unregulated wearable sensors used to gather physiological and movement data. Sensors to monitor certain vital signs (e.g. heart rate and respiratory rate) could be deployed, for instance, when monitoring patients with congestive heart failure or patients with chronic obstructive pulmonary disease undergoing clinical intervention. Sensors for movement data capturing would be deployed, for instance, in applications such as monitoring the effectiveness of home-based rehabilitation interventions in stroke survivors or the use of mobility assistive devices in older adults.		x	x	x	

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III. Data input = an audio file					
i. App that analyzes an audio file of a person sleeping to evaluate symptoms of poor sleep, such as snoring and nocturnal delirium.		x			
ii. Computer-aided auscultation is software designed to assist physicians and other health professionals with decision making tasks when assessing a heart murmur. Data acquisition is done by capturing the input from the stethoscope and recording that data. The data is usually saved in a lossless WAV file format. Other formats where lossy compression techniques are used are not recommended such as MP3.				x	
iii. Using a digital recording of breath sounds, the software possesses automated techniques for lung sound analysis to understand the subtler characteristics of lung sounds and their potential correlations with physiological conditions. Based on such correlations, algorithms and tools serve as diagnostic aids. Conditions include various pulmonary diseases such as asthma, chronic obstructive pulmonary disease, and pneumonia.				x	

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IV. Data input = medical literature/guidelines and patient information					
a. Treatment option matching for professional use					
i. Basic symptoms/diagnosis/treatment option matching. There are numerous examples of software that merely seek to help the end-user make associations between observed symptoms and possible diagnosis and treatment options. The system logic is simply identifying linkages that have been published in the literature and programmed into the software.		x			
ii. Users enter clinical information into a text box, then the software looks for appropriate medical evidence in its knowledge base. The software offers a list of possible diagnoses based on symptoms, physician observations, test results, and other factors. Physicians can click a button to emphasize some findings over others in reaching a diagnosis.		x			
iii. Software that offers oncologists actionable insights based on molecular profile data, in the context of a patient's clinical history. In particular, the software allows an oncologist to: review patients' molecular & clinical history; order molecular testing; and select molecularly targeted therapies.		x			
iv. Drug selection software. This is a more specialized version that would be used in helping physicians pick the right drug for a given set of symptoms.		x			

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They might embody drug formulary guidelines or professional society treatment guidelines.					
v. Drug-drug interaction and drug-allergy contraindication alerts to avert adverse drug events--this could also fit in the EHR category below	FDASIA report	x			
vi. Evidence-based clinician order sets tailored for a particular condition, disease, or clinician preference. This may include recommendations based on institutions protocols.	FDASIA report	x			
vii. Software that embodies an antimicrobial stewardship initiative that help identify, for a particular patient, drug bug mismatches, redundant therapies and unnecessary double coverage of pathogens.		x			
viii. Automated system to mine MEDLINE for references to genes and proteins and to assess the relevance of each reference assignment		x			
ix. A software management system, which is based upon the principles of disease management and standardized nursing processes. The software maps out common disease categories. Each disease or affliction requires procedures to manage and improve outcomes. The system highlights abnormal findings and changes in condition and provides the nursing team with appropriate interventions and physician communication.		x			
b. Treatment option matching for consumer use					
i. Websites through which		x			

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consumers can enter symptoms and be informed of variety of possible associated diseases					
ii. Software that purports to offer a patient a definitive, singular either diagnosis or triage determination for a serious disease or condition on the basis of inputted symptoms.			x	x	
c. EHR-based CDS					
i. It is very common for this category to overlap with the treatment option category as you would have software that examines treatment options in light of what it finds in an EHR. Notice that we treat both categories similarly with regard to regulatory status		x			
ii. Duplicate testing alerts	FDASIA report	x			
iii. Suggestions for possible diagnoses based on patient-specific information retrieved from a patient's EHR-- this is basically the same as treatment option matching for professional use		x			
iv. Flagging or providing alerts when patient results fall outside of physician set parameters		x			

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V. Calculator software					
a. Humanly possible calculating software that automates something that a human could otherwise reasonably be expected to do					
i. Specialized calculator for prediction rules risk and severity of illness assessments. There are numerous examples of software that exists simply because a particular calculation is complicated or needs to be documented, and the purpose of the software is to help healthcare professionals do calculations that otherwise are time-consuming, as well as reducing the incidence of human calculation error. These would be calculations that are otherwise to be done by physicians manually, such as an Apgar score, APACHE score, AHRQ Pneumonia Severity Index, Charlson Index)	FDASIA report	x			
ii. Drug dosage calculator – professional use	FDASIA report	x			
iii. Drug dosage calculators – patient use. This could include things like an insulin bolus calculator that helps diabetic patients by calculating bolus insulin dose based on carbohydrate intake, pre-meal blood glucose, and anticipated physical activity reported to adjust carbohydrate ratio and basal insulin. (Class II) But there could also be drug dose calculators that would be in lower risk categories.	IMDRF Risk Document		x	x	
iv. Software that is intended as a radiation treatment planning system as an aid in treatment	IMDRF Risk Document			x	

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by using information from a patient and provides specific parameters that are tailored for a particular tumor and patient for treatment using a radiation medical device.					
v. Software that uses data from individuals for predicting risk score in high-risk population for developing preventive intervention strategies for colorectal cancer.	IMDRF Risk Document		x		
vi. Software that uses data from individuals for predicting risk score for developing stroke or heart disease for creating prevention or interventional strategies.	IMDRF Risk Document	x			
vii. Software that uses data from individuals for predicting risk score (functionality) in healthy populations for developing the risk (medical purpose) of migraine (a non-serious condition.)	IMDRF Risk Document	x			
viii. Software that allows for a detailed calculation of total body surface area (TBSA) burns for quick calculation of the amount of intravenous (IV) fluids required. The calculation is based on the Parkland Formula but the software does not explain the application of the Parkland Formula or the patient variables which lead to the specific recommendation(s).			x		
b. Complex data synthesizer that uses machine learning					
i. Large volume data analytics used urgently to guide clinical decision-making. Here it is the sheer volume of data and the complexity of the analysis that			x	x	

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make the software not transparent. In such a case, the actual classification of the software depends on the severity of the disease or the condition, and the role the software analytics plays in the diagnostic or treatment decision making. That said, because of the inherent competence of the professional users and their ability to think for themselves, such software would never cross into class III.					
ii. Software that applies a series of mathematical equations to analyze stores of clinical, administrative, or physiological data, then feeds the results into a computer model that simulates actual healthcare processes and human physiology. The software takes patient-specific data from more than 30 different variables to create "individualized guidelines" based on each person's unique risk factors, history, treatments, and, when available, biomarkers across multiple morbidities. The system can put together patient-specific care plans for better disease management.			x		
iii. Analyze patient history, presenting symptoms, and physician knowledge. The system looks for patterns in the data to produce a checklist, with statistical probabilities, for physicians to go through while making a differential diagnosis. Results are displayed in a dashboard view.			x		