



EPCS Prescriber Vendor Questionnaire

Please fill out as much information as possible and return to ecall@ibeta.com. The information provided will assist iBeta in providing a fixed price bid for EPCS certification. EPCS Certification is conducted in accordance with the DEA’s Interim Final Rule 21 CFR Parts 1300, 1304, 1306, and 1311.

Vendor		Legal name
System Name		Name of system for the title of the Certification Report
System Identifier		The subsystem identifier uniquely defines the implementation of the subsystem including for example a versioned model number or version ¹
Description		Brief description of the system under test
Functional description		Details functional description including inputs, outputs, input interface description, output interface description, physical and logical boundaries and security boundaries of the system.

¹ If an application provider has multiple versions of the application, all of which use the same code and controls for the functions that DEA is requiring, a single audit may be able to address multiple versions if other changes could not impact these functions.

In order to determine which requirements of the DEA’s interim final rule will be audited for compliance, please respond to the following questions by placing an ‘X’ in the Yes or No column.		Yes	No
Is the application system to be certified for prescribing or signing prescriptions?			
	Is the certification for a system for Individual Practitioners?		
	Is the certification for a system for Institutional Practitioners?		
	Will the system be used to prescribe Schedule II level prescriptions?		
	Will the system be used to prescribe Schedule III & IV level prescriptions?		
	Will the system be used to prescribe Schedule V level prescriptions?		
	Does the system support a written record of an emergency oral prescription?		
	Are e-prescription submitted directly to the Pharmacy (no intermediary)?		
	Are any e-prescription submitted through an intermediary?		
	Does the system support prescribing for a Schedule III, IV, or V narcotic drug approved by FDA specifically for “detoxification treatment” or “maintenance treatment”?		
	Is the system used to prescribe GHBA (Xyrem – Schedule III)?		
	Has the ID proofing for access control been established?		
	Does the practitioner use his/her own digital certificate (PKI) to sign an electronic controlled substance prescription? (If No then an application digital certificate is assumed)		
	What 2-factor credentials will be provided in the system under test?		
	Password		
	Hard token – please verify compliance to FIPS 140-2 Security Level 1		
Biometrics Please identify the modality			

Please list any additional information about the system that might be useful for iBeta to establish a proposal: