DRFIRST.COM, INC.
21 CFR COMPLIANCE REPORT

Report on DrFirst.com, Inc.'s Compliance with the Code of Federal Regulations Title 21 Parts 1300, 1304, 1306, and 1311

As of December 31, 2012

STRICTLY PRIVATE AND CONFIDENTIAL

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100 Park Avenue
New York, NY 10017
Phone 212-885-8000
Fax 212-697-1299

1. EXECUTIVE SUMMARY

January 8, 2013

To the Management of DrFirst.com, Inc.:

Scope

We have assessed DrFirst.com, Inc.'s ("DrFirst") compliance with the Code of Federal Regulations Title 21 ("21 CFR") Parts 1300, 1304, 1306, and 1311 as of December 31, 2012. During the course of our assessment, we have reviewed the design implementation of controls to achieve compliance with the 21 CFR Parts 1300, 1304, 1306, and 1311. Our procedures included examining, on a test basis, evidence about DrFirst's compliance with those requirements and performing such other procedures as we considered necessary in the circumstances.

Management of DrFirst is responsible for DrFirst.com, Inc.'s compliance with those requirements. Our assessment was conducted in accordance with consulting standards established by the American Institute of Certified Public Accountants. Our assessment does not provide a legal determination on DrFirst's compliance with the 21 CFR Parts 1300, 1304, 1306, and 1311.

Inherent Limitations

Because of their nature, controls at DrFirst may not prevent, or detect and correct, all errors or omissions in processing or reporting transactions. Also, the projection to the future of any evaluation of the controls, or conclusions about the suitability of the design of the controls to achieve compliance with the 21 CFR Parts 1300, 1304, 1306, and 1311 is subject to the risk that controls at DrFirst may become inadequate or fail.

Overall Results

During the course of our assessment, DrFirst has complied with the 21 CFR Parts 1300, 1304, 1306, and 1311 as of December 31, 2012, in all material respect.

Intended Users

This report is intended only for the information and use of DrFirst and Surescripts and is not intended to be and should not be used by anyone other than these specified parties.

2. DESCRIPTION OF CONTROL OBJECTIVES, CONTROLS, AND RESULTS OF COMPLIANCE

CONTROL OBJECTIVE 1 – 21 CFR PART 1300

*Controls provide reasonable assurance that DrFirst is com*plying with 21 CFR Part 1300.

	21 CFR PART 1300 REQUIREMENTS	DRFIRST CONTROL ACTIVITIES	COMPLIANCE EXCEPTIONS
1.1	Definitions relating to controlled substances, chemicals, electronic orders and prescriptions of controlled substances, and the dispensing of controlled substances via the Internet have been established and should be adhered to by practitioners and application service providers.	DrFirst has adopted the definitions relating to controlled substances established within the regulations by documenting them within the system's user documentation.	No relevant exceptions noted.

CONTROL OBJECTIVE 2 – 21 CFR PART 1304

*Controls provide reasonable assurance that DrFirst is com*plying with 21 CFR Part 1304.

	21 CFR PART 1304 REQUIREMENTS	DRFIRST CONTROL ACTIVITIES	COMPLIANCE EXCEPTIONS
2.1	1304.06.a.1 - The electronic prescription application must retain digitally signed record of the information specified in part 1306 of this chapter.	The Rcopia and EPCS audit logs contain the digital signature and full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, the name, address and registration number of the practitioner, and the date/time the prescription was signed for each controlled substance prescription issued by the system.	No relevant exceptions noted.
2.2	1304.06.a.2 - The electronic prescription application must retain the internal audit trail and any auditable event identified by the internal audit as required by §1311.150 of this chapter.	Auditable events including security incidents (unauthorized access, unauthorized modification / deletion of records, changes to user access) are recorded in the Rcopia and EPCS audit logs including the date and time of the event, the type of event, the identity of the person taking the action, where applicable, and the outcome of the event (success or failure).	No relevant exceptions noted.
2.3	1304.06.d - A registrant and application service provider must retain a copy of any security incident report filed with the Administration pursuant to §1311.150 and §1311.215 of this chapter.	A Corrective / Preventive Action form is filed and retained for any security incident identified by DrFirst personnel.	No relevant exceptions noted.
2.4	1304.06.e - An electronic prescription or pharmacy application provider must retain third party audit or certification reports as required by §1311.300 of this chapter.	Audit and certification logs and reports are maintained electronically for two years and archived for seven years in accordance with the Company's data retention policy.	No relevant exceptions noted.

CONTROL OBJECTIVE 2 – 21 CFR PART 1304

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	21 CFR PART 1304 REQUIREMENTS	DRFIRST CONTROL ACTIVITIES	COMPLIANCE EXCEPTIONS
2.5	1304.06.f - An application provider must retain a copy of any notification to the Administration regarding an adverse audit or certification report filed with the Administration on problems identified by the third-party audit or certification as required by §1311.300 of this chapter.	Refer to 2.4.	No relevant exceptions noted.
2.6	1304.06.g - Unless otherwise specified, records and reports must be retained for two years.	Refer to 2.4.	No relevant exceptions noted.

CONTROL OBJECTIVE 3 – 21 CFR PART 1306

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	21 CFR PART 1306 REQUIREMENTS	DRFIRST CONTROL ACTIVITIES	COMPLIANCE EXCEPTIONS
3.1	1306.05.a - All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address, and registration number of the practitioner.	Prescriptions for controlled substances are signed and dated when issued and contain the patient's name, address, drug name, strength, dosage, quantity prescribed, directions for use, and the name, address, and DEA number of the practitioner.	No relevant exceptions noted.
3.2	1306.05.b - A prescription for a Schedule III, IV, or V narcotic drug approved by FDA specifically for "detoxification treatment" or "maintenance treatment" must include the identification number issued by the Administrator under Sec. 1301.28(d) of this chapter or a written notice stating that the practitioner is acting under the good faith exception of Sec. 1301.28(e) of this chapter.	In order to issue a prescription for a Schedule III, IV, or V narcotic drugs, the prescriber must enter a Narcotics Addiction DEA Number within the prescription details.	No relevant exceptions noted.
3.3	1306.05.c - Where a prescription is for gamma-hydroxybutyric acid, the practitioner shall note on the face of the prescription the medical need of the patient for the prescription.	In order to issue a prescription for gamma-hydroxybutyric acid, the medical need must be entered within the prescription details.	No relevant exceptions noted.

CONTROL OBJECTIVE 4 – 21 CFR PART 1311

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	21 CFR PART 1311 REQUIREMENTS	DRFIRST CONTROL ACTIVITIES	COMPLIANCE EXCEPTIONS
4.1	1311.05.a.1 - Authentication: The system must enable a recipient to positively verify the signer without direct communication with the signer and subsequently demonstrate to a third party, if needed, that the sender's identity was properly verified.	A digital signature is applied to a prescription only after the prescriber successfully authenticates to the EPCS system with a hard or soft token and their corresponding passphrase.	No relevant exceptions noted.
4.2	1311.05.a.2 - Nonrepudiation: The system must ensure that strong and substantial evidence is available to the recipient of the sender's identity, sufficient to prevent the sender from successfully denying having sent the data. This criterion includes the ability of a third party to verify the origin of the document.	A digital signature is applied to a prescription to adequately support nonrepudiation. Also refer to 4.1.	No relevant exceptions noted.
4.3	1311.05.a.3 - Message integrity: The system must ensure that the recipient, or a third party, can determine whether the contents of the document have been altered during transmission or after receipt.	Refer to 4.40.	No relevant exceptions noted.

CONTROL OBJECTIVE 4 – 21 CFR PART 1311

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	21 CFR PART 1311 REQUIREMENTS	DRFIRST CONTROL ACTIVITIES	COMPLIANCE EXCEPTIONS
4.4	1311.55.d - For systems used to process CSOS orders, the system developer or vendor must have an initial independent third-party audit of the system and an additional independent third-party audit whenever the signing or verifying functionality is changed to determine whether it correctly performs the functions listed under paragraphs (b) and (c) of this section. The system developer must retain the most recent audit results and retain the results of any other audits of the software completed within the previous two years.	A compliance attestation against 21 CFR Part 1311 by an independent third party was completed as a part of the initial release of the system. Whenever the signing or verifying functionality of the system is changed, a compliance attestation against 21 CFR Part 1311 by an independent third party will be completed. Also refer to 2.4 related to the archival of audit reports.	No relevant exceptions noted.
4.5	1311.115.a - To sign a controlled substance prescription, the electronic prescription application must require the practitioner to authenticate to the application using an authentication protocol that uses two of the following three factors: (1) Something only the practitioner knows, such as a password or response to a challenge question. (2) Something the practitioner is, biometric data such as a fingerprint or iris scan. (3) Something the practitioner has, a device (hard token) separate from the computer to which the practitioner is gaining access.	Refer to 4.1.	No relevant exceptions noted.

CONTROL OBJECTIVE 4 – 21 CFR PART 1311

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	21 CFR PART 1311 REQUIREMENTS	DRFIRST CONTROL ACTIVITIES	COMPLIANCE EXCEPTIONS
4.6	1311.115.b - If one factor is a hard token, it must be separate from the computer to which it is gaining access and must meet at least the criteria of FIPS 140–2 Security Level 1, as incorporated by reference in §1311.08, for cryptographic modules or one-time-password devices.	Digital signatures for controlled substance prescriptions are created using encryption software certified by the National Institute of Standards and Technology ("NIST") that adheres to the FIPS 140-2 standard.	No relevant exceptions noted.
4.7	1311.120.b.1 - The electronic prescription application must do the following: (i) Link each registrant, by name, to at least one DEA registration number. (ii) Link each practitioner exempt from registration to the institutional practitioner's DEA registration number and the specific internal code number required under this chapter.	As a part of the user registration process for the EPCS system, providers must input their DEA registration number before proceeding with the on boarding process. The user registration form contains multiple field validations to minimize the number of data entry errors.	No relevant exceptions noted.
4.8	1311.120.b.2 - The electronic prescription application must be capable of the setting of logical access controls to limit permissions for the following functions: (i) Indication that a prescription is ready for signing and signing controlled substance prescriptions. (ii) Creating, updating, and executing the logical access controls for the functions.	Access to sign controlled substance prescriptions is limited to providers who have successfully completed the on-boarding process. Access to the Logical Access module of EPCS is limited to DrFirst IT Support personnel.	No relevant exceptions noted.

CONTROL OBJECTIVE 4 – 21 CFR PART 1311

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	21 CFR PART 1311 REQUIREMENTS	DRFIRST CONTROL ACTIVITIES	COMPLIANCE EXCEPTIONS
4.9	1311.120.b.4 - The application must require that the setting and changing of logical access controls specified under paragraph (b)(2) of this section involve the actions of two individuals as specified in §1311.125 or §1311.130. Except for institutional practitioners, a practitioner authorized to sign controlled substance prescriptions must approve logical access control entries.	Two individuals, one of whom is a practitioner authorized to sign controlled substance prescriptions, are required to approve access to the EPCS system.	No relevant exceptions noted.
4.10	1311.120.b.5 - The electronic prescription application must accept two-factor authentication that meets the requirements of §1311.115 and require its use for signing controlled substance prescriptions and for approving data that set or change logical access controls related to reviewing and signing controlled substance prescriptions.	Practitioners must enter their PIN from their hard or soft token and their corresponding passphrase in order to sign controlled substance prescriptions or approve logical access changes to the system.	No relevant exceptions noted.
4.11	1311.120.b.6 - The electronic prescription application must be capable of recording all of the applicable information required in part 1306 of this chapter for the controlled substance prescription.	Refer to 3.1.	No relevant exceptions noted.
4.12	1311.120.b.8 - The electronic prescription application must have a time application that is within five minutes of the official National Institute of Standards and Technology time source.	The NetTime time synchronization tool is installed on all DrFirst production servers to align each device's time to the official NIST time source.	No relevant exceptions noted.

CONTROL OBJECTIVE 4 – 21 CFR PART 1311

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	21 CFR PART 1311 REQUIREMENTS	DRFIRST CONTROL ACTIVITIES	COMPLIANCE EXCEPTIONS
4.13	1311.120.b.9 - The electronic prescription application must present for the practitioner's review and approval all of the following data for each controlled substance prescription: (i) The date of issuance. (ii) The full name of the patient. (iii) The drug name. (iv) The dosage strength and form, quantity prescribed, and directions for use. (v) The number of refills authorized, if applicable, for prescriptions for Schedule III, IV, and V controlled substances. (vi) For prescriptions written in accordance with the requirements of §1306.12(b) of this chapter, the earliest date on which a pharmacy may fill each prescription. (vii) The name, address, and DEA registration number of the prescribing practitioner. (viii) The statement required under §1311.140(a)(3).	The Controlled Substance Prescription Signing Screen ("CSPSS") contains the date of issuance, full name of patient, drug name, dosage strength, form, quantity prescribed, directions for use, number of refills authorized, earliest fill date by pharmacy, prescriber's name, address, and DEA number, and the statement "By completing the two-factor authentication protocol at this time, you are legally signing the prescription(s) and authorizing the transmission of the above information to the pharmacy for dispensing. The two-factor authentication protocol may only be completed by the practitioner whose name and DEA registration number appear above." These items remain displayed until the practitioner signs using two factor authentication or cancels the prescription.	No relevant exceptions noted.

CONTROL OBJECTIVE 4 – 21 CFR PART 1311

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	21 CFR PART 1311 REQUIREMENTS	DRFIRST CONTROL ACTIVITIES	COMPLIANCE EXCEPTIONS
4.14	1311.120.b.10 - The electronic prescription application must require the prescribing practitioner to indicate that each controlled substance prescription is ready for signing. The electronic prescription application must not permit alteration of the DEA elements after the practitioner has indicated that a controlled substance prescription is ready to be signed without requiring another review and indication of readiness for signing. Any controlled substance prescription not indicated as ready to be signed shall not be signed or transmitted.	The practitioner must individually select by checking the box next to each controlled substance prescription that is ready for signing in order to proceed to the CSPSS. The data elements within the CSPSS are read-only and cannot be altered prior to signing and transmission. Completion of the two-factor authentication via PIN and passphrase and pressing the "Sign and Send" button causes the prescription to be signed, transmitted, and archived.	No relevant exceptions noted.
4.15	1311.120.b.11 - While the information required by paragraph (b)(9) of this section and the statement required by §1311.140(a)(3) remain displayed, the electronic prescription application must prompt the prescribing practitioner to authenticate to the application, using two-factor authentication, as specified in §1311.140(a)(4), which will constitute the signing of the prescription by the practitioner for purposes of §1306.05(a) and (e) of this chapter.	Refer to 4.1 and 4.13.	No relevant exceptions noted.

CONTROL OBJECTIVE 4 – 21 CFR PART 1311

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	21 CFR PART 1311 REQUIREMENTS	DRFIRST CONTROL ACTIVITIES	COMPLIANCE EXCEPTIONS
4.16	1311.120.b.12 - The electronic prescription application must not permit a practitioner other than the prescribing practitioner whose DEA number (or institutional practitioner DEA number and extension data for the individual practitioner) is listed on the prescription as the prescribing practitioner and who has indicated that the prescription is ready to be signed to sign the prescription.	The EPCS system validates the prescribing practitioner's PIN and passphrase to ensure that another practitioner cannot sign on their behalf. The PIN and passphrase are not cached for potential reuse and must be reentered for each prescription. Other roles within Rcopia including the provider agent do not have the ability to sign controlled substance prescriptions.	No relevant exceptions noted.
4.17	1311.120.b.13 - Where a practitioner seeks to prescribe more than one controlled substance at one time for a particular patient, the electronic prescription application may allow the practitioner to sign multiple prescriptions for a single patient at one time using a single invocation of the two-factor authentication protocol provided the following has occurred: The practitioner has individually indicated that each controlled substance prescription is ready to be signed while the information required by paragraph (b)(9) of this section for each such prescription is displayed along with the statement required by §1311.140(a)(3).	Refer to 4.14.	No relevant exceptions noted.

CONTROL OBJECTIVE 4 – 21 CFR PART 1311

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	21 CFR PART 1311 REQUIREMENTS	DRFIRST CONTROL ACTIVITIES	COMPLIANCE EXCEPTIONS
4.18	1311.120.b.14 - The electronic prescription application must time and date stamp the prescription when the signing function is used.	Refer to 2.1.	No relevant exceptions noted.
4.19	1311.120.b.15 - When the practitioner uses his two-factor authentication credential as specified in §1311.140(a)(4), the electronic prescription application must digitally sign at least the information required by part 1306 of this chapter and electronically archive the digitally signed record. If the practitioner signs the prescription with his own private key, as provided in §1311.145, the electronic prescription application must electronically archive a copy of the digitally signed record, but need not apply the application's digital signature to the record.	Refer to 2.1.	No relevant exceptions noted.

CONTROL OBJECTIVE 4 – 21 CFR PART 1311

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	21 CFR PART 1311 REQUIREMENTS	DRFIRST CONTROL ACTIVITIES	COMPLIANCE EXCEPTIONS
4.20	1311.120.b.16 - The digital signature functionality must meet the following requirements: (i) The cryptographic module used to digitally sign the data elements required by part 1306 of this chapter must be at least FIPS 140–2 Security Level 1 validated. FIPS 140–2 is incorporated by reference in §1311.08. (ii) The digital signature application and hash function must comply with FIPS 186–3 and FIPS 180–3, as incorporated by reference in §1311.08. (iii) The electronic prescription application's private key must be stored encrypted on a FIPS 140–2 Security Level 1 or higher validated cryptographic module using a FIPS-approved encryption algorithm. FIPS 140–2 is incorporated by reference in §1311.08. (iv) For software implementations, when the signing module is deactivated, the application must clear the plain text password from the application memory to prevent the unauthorized access to, or use of, the private key.	Refer to 4.6.	No relevant exceptions noted.

CONTROL OBJECTIVE 4 – 21 CFR PART 1311

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	21 CFR PART 1311 REQUIREMENTS	DRFIRST CONTROL ACTIVITIES	COMPLIANCE EXCEPTIONS
4.21	1311.120.b.18 - The electronic prescription application must not transmit a controlled substance prescription unless the signing function described in §1311.140(a)(4) has been used.	The "Sign and Send" function on the CSPSS which applies the signature and transmits the prescription is not enabled until the practitioner has entered a PIN and passphrase.	No relevant exceptions noted.
4.22	1311.120.b.19 - The electronic prescription application must not allow alteration of any of the information required by part 1306 of this chapter after the prescription has been digitally signed. Any alteration of the information required by part 1306 of this chapter after the prescription is digitally signed must cancel the prescription.	Refer to 4.14.	No relevant exceptions noted.
4.23	1311.120.b.20 - The electronic prescription application must not allow transmission of a prescription that has been printed.	The Send function within Rcopia is disabled for controlled substance prescriptions that have been printed.	No relevant exceptions noted.
4.24	1311.120.b.21 - The electronic prescription application must allow printing of a prescription after transmission only if the printed prescription is clearly labeled as a copy not for dispensing. The electronic prescription application may allow printing of prescription information if clearly labeled as being for informational purposes. The electronic prescription application may transfer such prescription information to medical records.	Attempting to print a prescription after it has been transmitted results in the removal of the signature line, a warning on the prescription stating that it has already been sent, and a watermark on the actual printed copy stating, "Copy Not Valid For Dispensing".	No relevant exceptions noted.

CONTROL OBJECTIVE 4 – 21 CFR PART 1311

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	21 CFR PART 1311 REQUIREMENTS	DRFIRST CONTROL ACTIVITIES	COMPLIANCE EXCEPTIONS
4.25	1311.120.b.22 - If the transmission of an electronic prescription fails, the electronic prescription application may print the prescription. The prescription must indicate that it was originally transmitted electronically to, and provide the name of, a specific pharmacy, the date and time of transmission, and that the electronic transmission failed.	A message is included on the printed copy of a prescription whose transmission fails indicating the failure, pharmacy, and date / time of the attempted transmission.	No relevant exceptions noted.
4.26	1311.120.b.23 - The electronic prescription application must maintain an audit trail of all actions related to the following: (i) The creation, alteration, indication of readiness for signing, signing, transmission, or deletion of a controlled substance prescription. (ii) Any setting or changing of logical access control permissions related to the issuance of controlled substance prescriptions. (iii) Notification of a failed transmission. (iv) Auditable events as specified in §1311.150.	Refer to 2.2.	No relevant exceptions noted.

CONTROL OBJECTIVE 4 – 21 CFR PART 1311

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	21 CFR PART 1311 REQUIREMENTS	DRFIRST CONTROL ACTIVITIES	COMPLIANCE EXCEPTIONS
4.27	1311.120.b.24 - The electronic prescription application must record within each audit record the following information: (i) The date and time of the event. (ii) The type of event. (iii) The identity of the person taking the action, where applicable. (iv) The outcome of the event (success or failure).	Refer to 2.2.	No relevant exceptions noted.
4.28	1311.120.b.25 - The electronic prescription application must conduct internal audits and generate reports on any of the events specified in §1311.150 in a format that is readable by the practitioner. Such internal audits may be automated and need not require human intervention to be conducted.	Upon request, DrFirst will provide security incident reports and detail from the audit log to practitioners. Also refer to 2.2 for records and fields included within the audit log.	No relevant exceptions noted.
4.29	1311.120.b.26 - The electronic prescription application must protect the stored audit records from unauthorized deletion. The electronic prescription application shall prevent modifications to the audit records.	The audit log is stored in a secure database separate from the production database with multiple preventative controls to limit access. Each record in the audit log contains a hash which will identify any attempt to change or delete records.	No relevant exceptions noted.

CONTROL OBJECTIVE 4 – 21 CFR PART 1311

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	21 CFR PART 1311 REQUIREMENTS	DRFIRST CONTROL ACTIVITIES	COMPLIANCE EXCEPTIONS
4.30	1311.120.b.27 - The electronic prescription application must do the following: (i) Generate a log of all controlled substance prescriptions issued by a practitioner during the previous calendar month and provide the log to the practitioner no later than seven calendar days after that month. (ii) Be capable of generating a log of all controlled substance prescriptions issued by a practitioner for a period specified by the practitioner upon request. Prescription information available from which to generate the log must span at least the previous two years. (iii) Archive all logs generated. (iv) Ensure that all logs are easily readable or easily rendered into a format that a person can read. (v) Ensure that all logs are sortable by patient name, drug name, and date of issuance of the prescription.	A reporting interface is available that allows practitioners to generate a readable log of all scheduled (controlled substance) prescriptions during the previous month and up to the previous two years. Logs are sortable by patient name, drug name, and issue date. Also refer to 2.4 regarding archiving of logs.	No relevant exceptions noted.
4.31	1311.120.b.28 - Where the electronic prescription application is required by this part to archive or otherwise maintain records, it must retain such records electronically for two years from the date of the record's creation and comply with all other requirements of §1311.305.	Refer to 2.4.	No relevant exceptions noted.

CONTROL OBJECTIVE 4 – 21 CFR PART 1311

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	21 CFR PART 1311 REQUIREMENTS	DRFIRST CONTROL ACTIVITIES	COMPLIANCE EXCEPTIONS
4.32	1311.140.a.3 - While the prescription information required in §1311.120(b)(9) is displayed, the following statement or its substantial equivalent is displayed: “By completing the two-factor authentication protocol at this time, you are legally signing the prescription(s) and authorizing the transmission of the above information to the pharmacy for dispensing. The two-factor authentication protocol may only be completed by the practitioner whose name and DEA registration number appear above.”	Refer to 4.13.	No relevant exceptions noted.
4.33	1311.140.a.6 - Except as provided under §1311.145, the practitioner's completion of the two-factor authentication protocol must cause the application to digitally sign and electronically archive the information required under part 1306 of this chapter.	Refer to 4.14.	No relevant exceptions noted.
4.34	1311.140.b - The electronic prescription application must clearly label as the signing function the function that prompts the practitioner to execute the two-factor authentication protocol using his credential.	Refer to 4.14.	No relevant exceptions noted.
4.35	1311.145.d - The electronic prescription application must electronically archive the digitally signed record.	Refer to 2.1 and 4.14.	No relevant exceptions noted.

CONTROL OBJECTIVE 4 – 21 CFR PART 1311

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	21 CFR PART 1311 REQUIREMENTS	DRFIRST CONTROL ACTIVITIES	COMPLIANCE EXCEPTIONS
4.36	1311.145.f - If the electronic prescription is transmitted without the digital signature, the electronic prescription application must check the certificate revocation list of the certification authority that issued the practitioner's digital certificate. If the digital certificate is not valid, the electronic prescription application must not transmit the prescription. The certificate revocation list may be cached until the certification authority issues a new certificate revocation list.	The system validates the prescription's digital signature internally before applying DrFirst's application level certificate and transmitting to Surescripts.	No relevant exceptions noted.
4.37	1311.150.a - The application provider must establish and implement a list of auditable events. Auditable events must, at a minimum, include the following: (1) Attempted unauthorized access to the electronic prescription application, or successful unauthorized access where the determination of such is feasible. (2) Attempted unauthorized modification or destruction of any information or records required by this part, or successful unauthorized modification or destruction of any information or records required by this part where the determination of such is feasible. (3) Interference with application operations of the	Refer to 2.2.	No relevant exceptions noted.

CONTROL OBJECTIVE 4 – 21 CFR PART 1311

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	21 CFR PART 1311 REQUIREMENTS	DRFIRST CONTROL ACTIVITIES	COMPLIANCE EXCEPTIONS
	prescription application. (4) Any setting of or change to logical access controls related to the issuance of controlled substance prescriptions. (5) Attempted or successful interference with audit trail functions. (6) For application service providers, attempted or successful creation, modification, or destruction of controlled substance prescriptions or logical access controls related to controlled substance prescriptions by any agent or employee of the application service provider. (b) The electronic prescription application must analyze the audit trail at least once every calendar day and generate an incident report that identifies each auditable event. (c) Any person designated to set logical access controls under §§1311.125 or 1311.130 must determine whether any identified auditable event represents a security incident that compromised or could have compromised the integrity of the prescription records. Any such incidents must be reported to the electronic prescription application provider and the Administration within one business day.		

CONTROL OBJECTIVE 4 – 21 CFR PART 1311

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	21 CFR PART 1311 REQUIREMENTS	DRFIRST CONTROL ACTIVITIES	COMPLIANCE EXCEPTIONS
4.38	1311.170.c - The electronic prescription application may print copies of the transmitted prescription if they are clearly labeled: "Copy only—not valid for dispensing." Data on the prescription may be electronically transferred to medical records, and a list of prescriptions written may be printed for patients if the list indicates that it is for informational purposes only and not for dispensing.	Refer to 4.24.	No relevant exceptions noted.
4.39	1311.170.d - The electronic prescription application must not allow the transmission of an electronic prescription if an original prescription was printed prior to attempted transmission.	Refer to 4.23.	No relevant exceptions noted.
4.40	1311.170.e - The contents of the prescription required by part 1306 of this chapter must not be altered during transmission between the practitioner and pharmacy. Any change to the content during transmission, including truncation or removal of data, will render the electronic prescription invalid. The electronic prescription data may be converted from one software version to another between the electronic prescription application and the pharmacy application; conversion includes altering the structure of fields or machine language so that the receiving pharmacy application can read the prescription and import the data.	DrFirst utilizes a dedicated Secure Sockets Layer connection with Surescripts to transmit prescriptions which encrypts the data and protects it from alteration during transmission.	No relevant exceptions noted.

CONTROL OBJECTIVE 4 – 21 CFR PART 1311

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	21 CFR PART 1311 REQUIREMENTS	DRFIRST CONTROL ACTIVITIES	COMPLIANCE EXCEPTIONS
4.41	1311.170.f - An electronic prescription must be transmitted from the practitioner to the pharmacy in its electronic form. At no time may an intermediary convert an electronic prescription to another form (e.g., facsimile) for transmission.	The ability to fax prescriptions has been disabled for controlled substances.	No relevant exceptions noted.