

FEDLINE 2021 FEE SCHEDULE—Continued

[Effective January 4, 2021. **Bold indicates changes from 2020 prices.**]

	Fee
51–100 respondents and/or sub-accounts .....	\$500.00.
101–500 respondents and/or sub-accounts .....	\$750.00.
>500 respondents and/or sub-accounts .....	\$1,000.00.
End-of-Day Financial Institution Reconciliation Data (FIRD) File <sup>86</sup> .....	\$150.00.
Statement of Account Spreadsheet File <sup>87</sup> .....	\$150.00.
Intra-day Download Search File (with AMI) <sup>88</sup> .....	\$150.00.
Other:	
Software Certification .....	\$0.00 to \$8,000.00.
Vendor Pass-Through Fee .....	various.
Electronic Access Credit Adjustment .....	various.
Electronic Access Debit Adjustment .....	various.

By order of the Board of Governors of the Federal Reserve System.

**Ann Misback,**

*Secretary of the Board.*

[FR Doc. 2020–25176 Filed 11–13–20; 8:45 am]

**BILLING CODE P**

<sup>57</sup> The incentive discounts apply to the volume that exceeds 60 percent of a customer's historic benchmark volume. Historic benchmark volume is based on a customer's average daily activity over the previous five calendar years. If a customer has fewer than five full calendar years of previous activity, its historic benchmark volume is based on its daily activity for as many full calendar years of data as are available. If a customer has less than one year of past activity, then the customer qualifies automatically for incentive discounts for the year. The applicable incentive discounts are as follows: \$0.672 for transfers up to 14,000; \$0.200 for transfers 14,001 to 90,000; and \$0.132 for transfers over 90,000.

<sup>58</sup> This surcharge applies to originators of transfers that are processed by the Reserve Banks after 5:00 p.m. eastern time.

<sup>59</sup> This fee is charged to any Fedwire Funds participant that originates a transfer message via the FedPayments Manager (FPM) Funds tool and has the import/export processing option setting active at any point during the month.

<sup>60</sup> Payment Notification and End-of-Day Origination surcharges apply to each Fedwire funds transfer message.

<sup>61</sup> Provided on billing statement for informational purposes only.

<sup>62</sup> This charge is assessed to settlement arrangements that use the Fedwire Funds Service to effect the settlement of interbank obligations (as opposed to those that use the National Settlement Service). With respect to such special settlement arrangements, other charges may be assessed for each funds transfer into or out of the accounts used in connection with such arrangements.

<sup>63</sup> If your organization is a settlement agent, it may be able to use the NSS offline service if it is experiencing an operational event that prevents the transmission of settlement files via its electronic connection to the Federal Reserve Banks. The Federal Reserve Banks have limited capacity to process offline settlement files. As a result, while the Federal Reserve Banks use best efforts to process offline settlement file submissions, there is no guarantee that an offline settlement file, in particular one that is submitted late in the operating day or that contains a large number of entries, will be accepted for processing. Only those persons identified as authorized individuals on the NSS 04 Agent Contact Form may submit offline settlement files. For questions related to the NSS offline service, please contact NSS Central Support Service Staff (CSSS) at 800–758–9403, or via email at [csss.staff@ny.frb.org](mailto:csss.staff@ny.frb.org).

<sup>64</sup> Any settlement arrangement that accrues less than \$60 during a calendar month will be assessed a variable amount to reach the minimum monthly fee.

<sup>65</sup> These fees are set by the Federal Reserve Banks.

<sup>66</sup> This surcharge is set by the Federal Reserve Banks. It is in addition to any basic transfer or reversal fee.

<sup>67</sup> The Federal Reserve Banks offer an automated claim adjustment process only for Agency mortgage-backed securities.

<sup>68</sup> This fee is set by and remitted to the Government National Mortgage Association (GNMA).

<sup>69</sup> The Federal Reserve Banks charge participants a Joint Custody Origination Surcharge for both Agency and Treasury securities.

<sup>70</sup> FedComplete customers that use the email service would be charged the FedMail Email a la carte fee and for all FedMail-FedLine Exchange Subscriber 5-packs.

<sup>71</sup> FedComplete packages are all-electronic service options that bundle payment services with an access solution for one monthly fee.

<sup>72</sup> Packages with an "A" include the FedLine Advantage channel, and packages with "C" include the FedLine Command channel.

<sup>73</sup> Per-item surcharges are in addition to the standard fees listed in the applicable priced services fee schedules.

<sup>74</sup> FedComplete customers will be charged \$4 for each FedForward cash letter over the monthly package threshold. This activity will appear under billing code 51998 in Service Area 1521 on a month-lagged basis.

<sup>75</sup> FedMail and FedLine Exchange packages do not include user credentials, which are required to access priced services and certain informational services. Credentials are sold separately in packs of five via the FedMail-FedLine Exchange Subscriber 5-pack.

<sup>76</sup> FedLine Web and Advantage packages do not include user credentials, which are required to access priced services and certain informational services. Credentials are sold separately in packs of five via the FedLine Subscriber 5-pack.

<sup>77</sup> Early termination fees and/or expedited order fees may apply to all FedLine Direct packages and FedLine Direct a la carte options.

<sup>78</sup> These add-on services can be purchased only with a FedLine Solutions packages.

<sup>79</sup> Additional VPNs are available for FedLine Advantage, FedLine Command, and FedLine Direct packages only.

<sup>80</sup> These upgrades are only available for the new FedLine Direct packages and the Add'l 2M WAN connection. Fee is in addition to the FedLine Direct package fees or additional WAN fees.

<sup>81</sup> The FedLine Custom Implementation Fee is \$2,500 or \$5,000 based on the complexity of the setup.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Statement of Organization, Functions, and Delegations of Authority**

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 85 FR 30106–30708, dated May 20, 2020) is amended to reflect the reorganization of the Division of Sexually Transmitted Disease Prevention within the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention.

Section C–B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the titles and mission and function statements for the *Division of Sexually Transmitted Disease Prevention (CVJD)* and insert the following:

<sup>82</sup> Available only to customers with a priced FedLine package.

<sup>83</sup> Limited to installed base only.

<sup>84</sup> Five download codes are included at no cost in all Plus and Premier packages.

<sup>85</sup> Cash Management Service options are limited to plus and premier packages.

<sup>86</sup> The End of Day Reconciliation File option is available for FedLine Web Plus, FedLine Advantage Plus, and Premier packages. It is available for no extra fee in FedLine Command Plus and Direct packages.

<sup>87</sup> The Statement of Account Spreadsheet File option is available for FedLine Web Plus, FedLine Advantage Plus, and Premier packages. It is available for no extra fee in FedLine Command Plus and Direct packages.

<sup>88</sup> The Intra-day Download Search File option is available for the FedLine Web Plus package. It is available for no extra fee in FedLine Advantage and higher packages.

*Division of Sexually Transmitted Disease Prevention (CVJD).* (1) In cooperation with other CDC components, administers operational programs for the prevention of sexually transmitted diseases (STD); (2) provides consultation, training, statistical, educational, epidemiological, and other technical services to assist state and local health departments in the planning, development, implementation, evaluation, and overall improvement of STD prevention programs; (3) supports a nationwide framework for effective surveillance of STD other than HIV; (4) conducts behavioral, clinical, epidemiological, preventive health services, and operational research into factors affecting the prevention and control of STD; (5) provides leadership and coordinates, in collaboration with other CDC components, research and program activities that focus on STD and HIV prevention; (6) promotes linkages between health department STD programs and other governmental and non-governmental partners who are vital to effective STD prevention efforts; (7) provides technical supervision for division, state and local assignees; and (8) collaborates with other components of the division, NCHHSTP and CDC to develop and implement strategies and activities to meet goals for key division priorities.

*Office of the Director (CVJD1).* (1) Plans, directs and evaluates the activities of the division; (2) provides national leadership and guidance in STD science, surveillance, prevention and control policy formulation; program planning, development, management, and evaluation; development of training, educational, and health communications; (3) provides operational, administrative, fiscal, technical, and logistical support for division programs and units; (4) assures multidisciplinary collaboration in STD prevention and control activities; (5) in cooperation with other CDC components, provides leadership for developing research relevant to STD prevention and control; (6) provides leadership, guidance, and coordinates development of guidelines and standards to assure ongoing high-quality performance of STD prevention and control programs; (7) coordinates global STD activity of the division; (8) collaborates, as appropriate, with other divisions and offices in NCHHSTP, and with other divisions throughout CDC; (9) collaborates as appropriate with external organizations outside of CDC to achieve the mission of the division; and

(10) manages the Tuskegee Participants Health Benefits Program.

*STD Laboratory Reference and Research Branch (CVJDE).* (1) Performs research on the pathogenesis, genetics, and immunology of syphilis, gonococcal and chlamydial infections, and other sexually transmitted infections (STI), including rare (e.g., chancroid) or emerging (e.g., *Mycoplasma genitalium*) STI; (2) conducts research and reference services to develop, evaluate, and improve laboratory STI diagnostics and methods; (3) participates in the design, implementation, and analysis of national and international STD epidemiology studies, surveillance activities, and biomedical interventions; (4) conducts laboratory-based surveillance for and research on the genetics of antimicrobial resistance in *Neisseria gonorrhoeae* and for other STIs; (5) serves as the WHO International Collaborating Center for Reference and Research in STI and as reference laboratory for WHO STD diagnostics and surveillance initiatives; and (6) develops STD laboratory guidelines.

*Program Development and Evaluation Branch (CVJDG).* (1) Provides and facilitates technical assistance and capacity building to state and local health departments, non-governmental, and other partners in the planning, implementation, and evaluation of STD prevention and control strategies; (2) monitors and evaluates STD prevention strategies to assure programmatic objectives are being met and to track individual and collective progress over time; (3) conducts analysis of STD prevention and control strategies and collaborates with partners to resolve challenges and increase awareness of best practices; (4) develops and manages programs, solicitations, and evaluation projects to advance innovations and quality improvements in STD prevention and control strategies and activities; and (5) supports the identification, translation, dissemination, and adoption of evidence-based interventions and practices by state and local health departments, non-governmental, and other prevention partners.

*Surveillance and Data Science Branch (CVJDH).* (1) Assesses and disseminates data on STD burden, risks, and trends in STD morbidity and mortality; (2) leads, evaluates, and provides recommendations for improving STD surveillance systems; (3) provides leadership in the management and coordination of information systems that can electronically receive, store, and transmit STD surveillance and case management data; (4) provides

surveillance, data management and public health informatics technical assistance and support to the division, local and state health departments, and other national and international partners; and (5) translates informatics best practices for STD electronic case reporting, clinical decision support, and other division efforts.

*Disease Intervention and Response Branch (CVJDI).* (1) Investigates STDs in the community (e.g., field testing, public health detailing, outbreak response, and contact tracing); (2) provides technical assistance and capacity in disease investigation to support communities and public health partners; (3) conducts activities to assure a competent disease investigation workforce (e.g., DIS certification, mentoring and training); and (4) provides linkage to services for STD prevention and control and other co-occurring activities (e.g., intimate partner violence, behavioral health, HIV care, PrEP, and reproductive health services).

*Behavioral Science and Epidemiology Branch (CVJDK).* (1) Synthesizes evidence and critically appraises existing prevention science research, as related to STD priorities; (2) identifies and describes the context for effective STD prevention science; (3) provides national and international leadership in the design and dissemination of studies to implement STD prevention interventions at individual, group, community, and structural levels; and (4) translates or adapts research strategies and evaluation results from formative assessments and prevention interventions for programmatic action and to inform national STD prevention policy and program direction.

*Clinical, Economics, and Health Services Research Branch (CVJDL).* (1) Develops and evaluates methodologies for conducting clinical, economic, modelling, and health services research related to STD prevention and control; (2) develops preventive clinical, health services, transmission dynamics, and cost-effectiveness models for STD-related issues; (3) estimates the economic and health impact burden of STDs and cost-effectiveness of STD prevention; (4) develops, disseminates, and evaluates STD prevention and clinical guidelines; (5) provides technical assistance, training, and capacity building pertaining to clinical and health services-related aspects of STD prevention; and (6) provides statistical research and technical

assistance to others in the division and to local and state STD control programs.

**Sherri Berger,**

*Chief Operating Officer, Centers for Disease Control and Prevention.*

[FR Doc. 2020–25194 Filed 11–13–20; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2019–D–3592]

#### Certificates of Confidentiality; Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled “Certificates of Confidentiality; Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff.” This guidance is intended to explain FDA implementation of the revised statutory provisions applicable to the request for, and issuance of, a Certificate of Confidentiality (CoC). The 21st Century Cures Act (Cures Act) amended the statutory provisions relating to the issuance of CoCs. A CoC is intended to help protect the privacy of human subject research participants from whom sensitive and identifiable information is being collected or used in furtherance of the research. Historically, a CoC generally protected a researcher from being compelled in a legal proceeding to disclose identifiable sensitive information about the research participant, created or compiled for the research. As amended, a CoC prohibits a researcher from disclosing such information unless a specified exception applies. This guidance finalizes the draft guidance of the same title issued on November 25, 2019.

**DATES:** The announcement of the guidance is published in the **Federal Register** on November 16, 2020.

**ADDRESSES:** You may submit either electronic or written comments on any guidance at any time as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

**Instructions:** All submissions received must include the Docket No. FDA–2019–D–3592 for “Certificates of Confidentiality; Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The

Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4248, Silver Spring, MD 20993–0002. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the final guidance document.

**FOR FURTHER INFORMATION CONTACT:** Jarilyn Dupont, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4248, Silver Spring, MD 20993–0002, 301–796–4716.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a final guidance to explain FDA’s implementation of the revised provisions applicable to the request for, and issuance of, a discretionary CoC. The Cures Act (Pub. L. 114–255, section 2012) amended the Public Health Service Act, section 301(d) (42 U.S.C. 241(d)), relating to the issuance of CoCs. A CoC is intended to help protect the privacy of human subject research participants from whom identifiable,