



mln call

A MEDICARE LEARNING NETWORK® (MLN) EVENT

Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Data Collection and Reporting Policies

Division of Ambulatory Services, Center for Medicare

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Acronyms in this Presentation

ADLT	Advanced Diagnostic Laboratory Test
AMA	American Medical Association
CBO	Congressional Budget Office
CDLT	Clinical Diagnostic Laboratory Test
CLFS	Clinical Laboratory Fee Schedule
CLIA	Clinical Laboratory Improvement Amendments
CMS	Centers for Medicare & Medicaid Services
CPT	AMA's Current Procedural Terminology
DNA	Deoxyribonucleic Acid
EIDM	Enterprise Identification Management
FDA	Food and Drug Administration
HCPCS	Healthcare Common Procedure Coding System
HHS	Health and Human Services
MAC	Medicare Administrative Contractor
MedCAC	Medicare Evidence Development and Coverage Advisory Committee
NLA	National Limitation Amount
NPI	National Provider Identifier
OIG	Office of Inspector General
PAMA	Protecting Access to Medicare Act of 2014
PFS	Physician Fee Schedule
RNA	Ribonucleic Acid



Agenda

1. Overview of Medicare Clinical Laboratory Fee Schedule (CLFS)
Private Payor Data Collection and Reporting Policies
2. Overview of Data Collection System
3. Question & Answer Session



CLFS Requirements

- On June 17, 2016 CMS published its final rule implementing section 216 of the Protecting Access to Medicare Act of 2014, which added a new section, 1834A, to the Social Security Act
- Requires private payor rates paid to applicable laboratories for clinical diagnostic laboratory tests to be reported to CMS and used to calculate Medicare payment rates



Definition of Applicable Laboratory

Statutory Provision

- PAMA defines laboratories subject to the new reporting requirements (“an applicable laboratory”) as having the majority of its Medicare revenues paid under the CLFS or the Physician Fee Schedule (PFS)
- Uses the Clinical Laboratory Improvement Amendments (CLIA) regulatory definition of laboratory
- Majority of Medicare revenues threshold



Definition of Applicable Laboratory (continued)

- National Provider Identifier (NPI) used to define applicable laboratory
- Tax Identification Number (TIN) required to report payment data
- Low Expenditure Threshold = \$12,500
- Majority of Medicare revenue and low expenditure thresholds are applied at NPI-level
- Low expenditure threshold does not apply to single laboratory furnishing Advanced Diagnostic Laboratory Tests (ADLTs), with respect to the ADLTs they furnish (explained more on later slides)



Revisions to the Definition of Applicable Laboratory

Final Physician Fee Schedule rule¹ published in 2018 made two revisions to the regulatory definition of “Applicable Laboratory”, effective January 1, 2019

(1) Medicare Advantage plan payments are excluded from total Medicare revenues (the denominator of the majority of Medicare revenues threshold)

(2) Hospital outreach laboratories that bill for their non-patient laboratory services using the hospital's NPI must use Medicare revenues from the Form CMS-1450 14x Type of Bill (TOB) to determine whether they meet the majority of Medicare revenues threshold and low expenditure threshold

¹ Physician Fee Schedule (PFS) final rule entitled “Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B for CY 2019” (CMS-1693-F)



Applicable Information

Includes:

- Specific Healthcare Common Procedure Coding System (HCPCS) code associated with the test
- Each private payor rate for which **final payment** has been made during a data collection period (by date of final payment)
- Number of tests performed for each private payor rate
 - Examples:
 - Multiple payment rates for the same test
 - Resolved Appeals
 - Non-contracted amounts for out-of-network laboratories or services
 - Final payments from secondary insurance payors



Applicable Information (continued)

- Applicable Information **Does Not** Include:
- Unresolved Appeals
- Payments that do not reflect specific HCPCS code-level amounts
- Remittances where the payor has grouped test-level payments into an encounter (claim-level) payment
- Denied Payments



Reporting Applicable Information

- TINs must report applicable information for all of its component applicable laboratories
- Voluntary reporting is not permitted (your lab must be applicable to submit data)
- Reporting applicable information is not discretionary



Private Payor Rate

- Includes
 - **ALL** payment rates
 - Final amount paid by a private payor for a CDLT after all private payor price concessions are applied
 - Only private payor payment rates for CDLTs paid for under the CLFS
 - Any patient cost sharing amounts, if applicable
- Does Not Include
 - Price concessions applied by a laboratory
 - Example: Waiving of patient deductible and or coinsurance.
 - Information about denied payments



Current/Upcoming Data Collection and Reporting Schedule

- Data collection period: January 1, 2019 through June 30, 2019
- Data reporting period: January 1, 2020 through March 31, 2020
- Payment rates implemented: January 1, 2021

Subsequent data collection and reporting

- Same timeline for each update year
 - Example: For update year CY 2024; data collection = January 1, 2022 – June 30, 2022
reporting = January 1, 2023 – March 31, 2023.



CLFS Payment Methodology for CDLTs

- CMS will calculate a weighted median private payor rate for each test
- Weighted median becomes the new CLFS payment rate
- If CMS receives no applicable information for a given CDLT or ADLT CMS will use crosswalking or gapfilling to price the test



Limitation on Payment Reduction for Existing Laboratory Tests

Statutory Requirements

- Limits reduction of the payment amount for existing tests prior to the implementation of the private payor rate-based CLFS (as compared to the payment amount for the preceding year)
- For upcoming payment cycle three years reduction is limited to 15 percent
- To determine the application of the phased-in payment reduction limit for a test, the weighted median private payor rate calculated for CY 2021 would be compared to the CY 2020 weighted median private payor rate

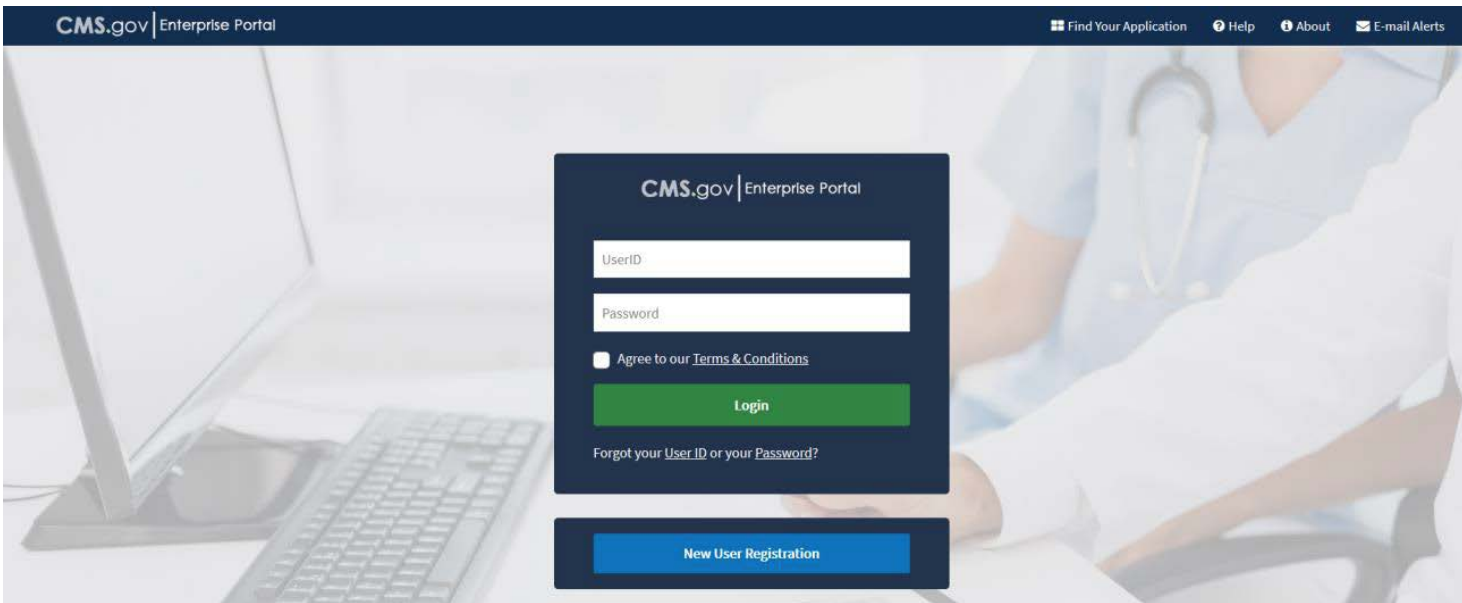


Confidentiality

- CMS and its contractors may not disclose reported applicable information in a form that would identify
 - A specific private payor or laboratory
 - Prices charged or payments made to a laboratory
- Exception: As CMS determines necessary to implement section 1834A of the Act and to permit the Comptroller General, the Director of the CBO, the HHS OIG, the MedPAC, or other law enforcement entities such as the Department of Justice to review the information



Registration – Choose system



The screenshot shows the CMS.gov Enterprise Portal interface. At the top, there is a dark blue header with the CMS.gov logo and 'Enterprise Portal' text. To the right of the header are links for 'Find Your Application', 'Help', 'About', and 'E-mail Alerts'. The main content area features a login form with fields for 'UserID' and 'Password', a checkbox for 'Agree to our Terms & Conditions', a green 'Login' button, and a link for 'Forgot your User ID or your Password?'. Below the login form is a blue 'New User Registration' button. The background of the page shows a blurred image of a healthcare professional in scrubs with a stethoscope.

Step #1: Choose Your Application

Step 1 of 3 - Select your application from the dropdown. You will then need to agree to the terms.

Choose Your Application



Registration – Choose role

Portal Help & FAQs | Print | Log Out | Welcome [User Name]

CMS.gov Enterprise Portal

My Portal

CMS Enterprise Portal > EIDM > User Menu > My Access

Screen reader mode Off | Accessibility Settings

My Access

- [Request New System Access](#)
- [View and Manage My Access](#)

Request New System Access

Select a System and then a role to request access.

* System Description: FFSDCS-The Fee for Service Data Col

* Role:

- Select the Role
- ASP Business Owner Representative
- ASP Certifier
- ASP End User
- ASP Helpdesk User
- ASP Staff
- CLFS Helpdesk
- CLFS Admin
- CLFS Staff
- CLFS Certifier
- CLFS Submitter

Please select a role

Cancel



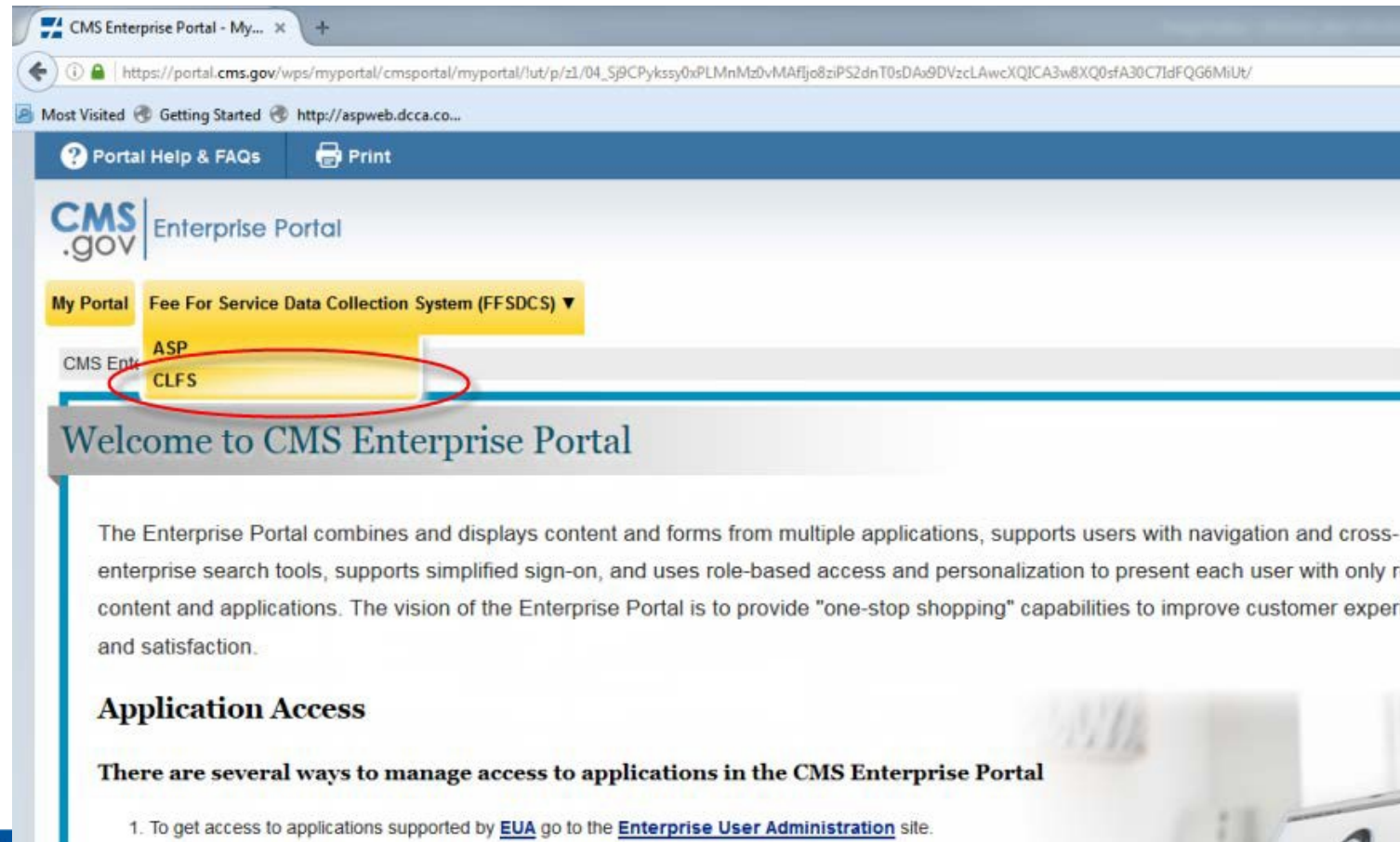
Registration – Role Approval

- After role submission – Please wait up to 72 hours, you will receive an email notification.
- Points of contact:
 - Application HelpDesk
 - Email: CLFSHelpDesk@dcca.com
 - Phone: 844-876-0765
 - 9AM-6PM Eastern, Non-Peak
 - 9AM-9PM Eastern, Peak (i.e., January-March)
 - Issue examples:
 - Account Unlock
 - Password Reset
 - **Registration process questions**
 - Policy Question escalations
 - System Availability escalations
 - Other



Registration – Role Approval Success

Choose CLFS system



CLFS Lab Registration

CLFS Submitter Role

- Applicable Laboratory Registration
 - Laboratory Name
 - Tax Identification Number (TIN) and type
 - All associated National Provider Identifiers (NPI)
 - All associated CMS Certification Numbers (CCN)

The screenshot shows the 'Laboratory Information' page of the 'Clinical Lab Fee Schedule' system. The page has a blue header with the title and a 'Help' link. A left sidebar contains navigation links: Home, Laboratory Information (selected), Data Reporting, Edit/View Data, Help, and Exit. The main content area is titled 'Laboratory Information' and includes a sub-header 'Laboratory Information' with a description: 'Please enter information about the laboratory for which you are reporting.' Below this is the 'CLFS Registration Input' section, which contains a form with the following fields: 'Username:' (pre-filled with 'John aong'), 'Laboratory Name*:', 'Tax Identification Number (TIN)*:', and 'TIN Type*:' (with a dropdown menu showing 'EIN'). Below the form is a section for 'Please enter all associated NPI's and CCN's that this laboratory will be reporting for.' This section has two columns: 'National Provider Identifier (NPI)*' with a link 'Add Additional NPI' and 'CMS Certification Number (CCN)' with a link 'Add Additional CCN'. Each column has a text input field. A 'Save' button is located below the input fields. At the bottom, there is a section titled 'Generate One Time Password' with a paragraph of instructions and a 'Generate One Time Password (OTP)' button.

Clinical Lab Fee Schedule **Laboratory Information** [Help](#)

[Home](#)
[Laboratory Information](#)
[Data Reporting](#)
[Edit/View Data](#)
[Help](#)
[Exit](#)

Laboratory Information
Please enter information about the laboratory for which you are reporting.

CLFS Registration Input

Username:	John aong
Laboratory Name*:	<input type="text"/>
Tax Identification Number (TIN)*:	<input type="text"/>
TIN Type*:	EIN <input type="button" value="v"/>

Please enter all associated NPI's and CCN's that this laboratory will be reporting for.

National Provider Identifier (NPI)* Add Additional NPI	CMS Certification Number (CCN) Add Additional CCN
<input type="text"/>	<input type="text"/>

Generate One Time Password

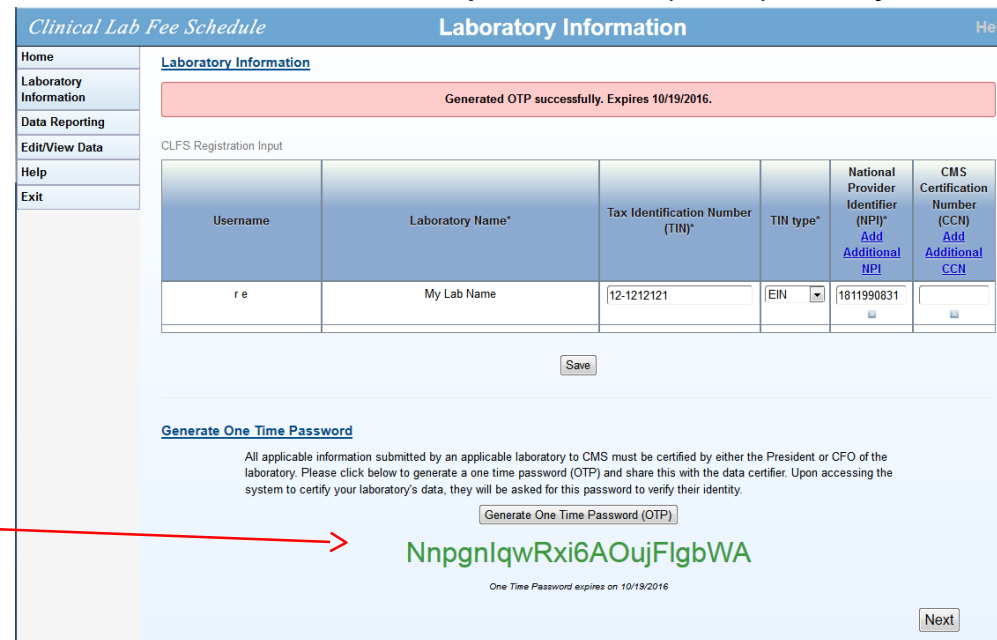
All applicable information submitted by an applicable laboratory to CMS must be certified by either the President or CFO of the laboratory. Please click below to generate a one time password (OTP) and share this with the data certifier. Upon accessing the system to certify your laboratory's data, they will be asked for this password to verify their identity.



CLFS Lab Registration

CLFS Submitter Verification

- Name of Submitter will be verified against the CMS Provider Enrollment Chain and Ownership System (PECOS) by the reporting TIN
- Your registration may require manual validation if the name verification fails.
 - Make sure PECOS is updated prior to EIDM registration
- Generate and share the one time password (OTP) with your certifier



The screenshot shows the 'Laboratory Information' page in the CLFS system. A red banner at the top indicates 'Generated OTP successfully. Expires 10/19/2016.' Below this, the 'CLFS Registration Input' table is displayed. A red arrow points from the 'Generate One Time Password' button to the generated OTP, 'NnpgnlqwRxi6AOujFlgbWA'.

Username	Laboratory Name*	Tax Identification Number (TIN)*	TIN type*	National Provider Identifier (NPI)* Add Additional NPI	CMS Certification Number (CCN) Add Additional CCN
r e	My Lab Name	12-1212121	EIN	1811990831	

[Generate One Time Password](#)

All applicable information submitted by an applicable laboratory to CMS must be certified by either the President or CFO of the laboratory. Please click below to generate a one time password (OTP) and share this with the data certifier. Upon accessing the system to certify your laboratory's data, they will be asked for this password to verify their identity.

[Generate One Time Password \(OTP\)](#)

NnpgnlqwRxi6AOujFlgbWA

One Time Password expires on 10/19/2016

[Next](#)



Applicable Information Submission

Clinical Lab Fee Schedule

Laboratory Information

Home

Laboratory Information

Data Reporting

Upload Applicable Information

Manual Entry Applicable Information

Edit/View Data

Help

Exit

Laboratory Information

CLFS Registration Input

Username	Laboratory Name*	Tax I
r e	My Lab Name	12-1212121

Save

Generate One Time Password

All applicable information submitted by an applicable laboratory to CMS must be certified by either the President or CFO of the laboratory. Please click I
Upon accessing the system to certify your laboratory's data, they will be asked for this password to verify their identity.



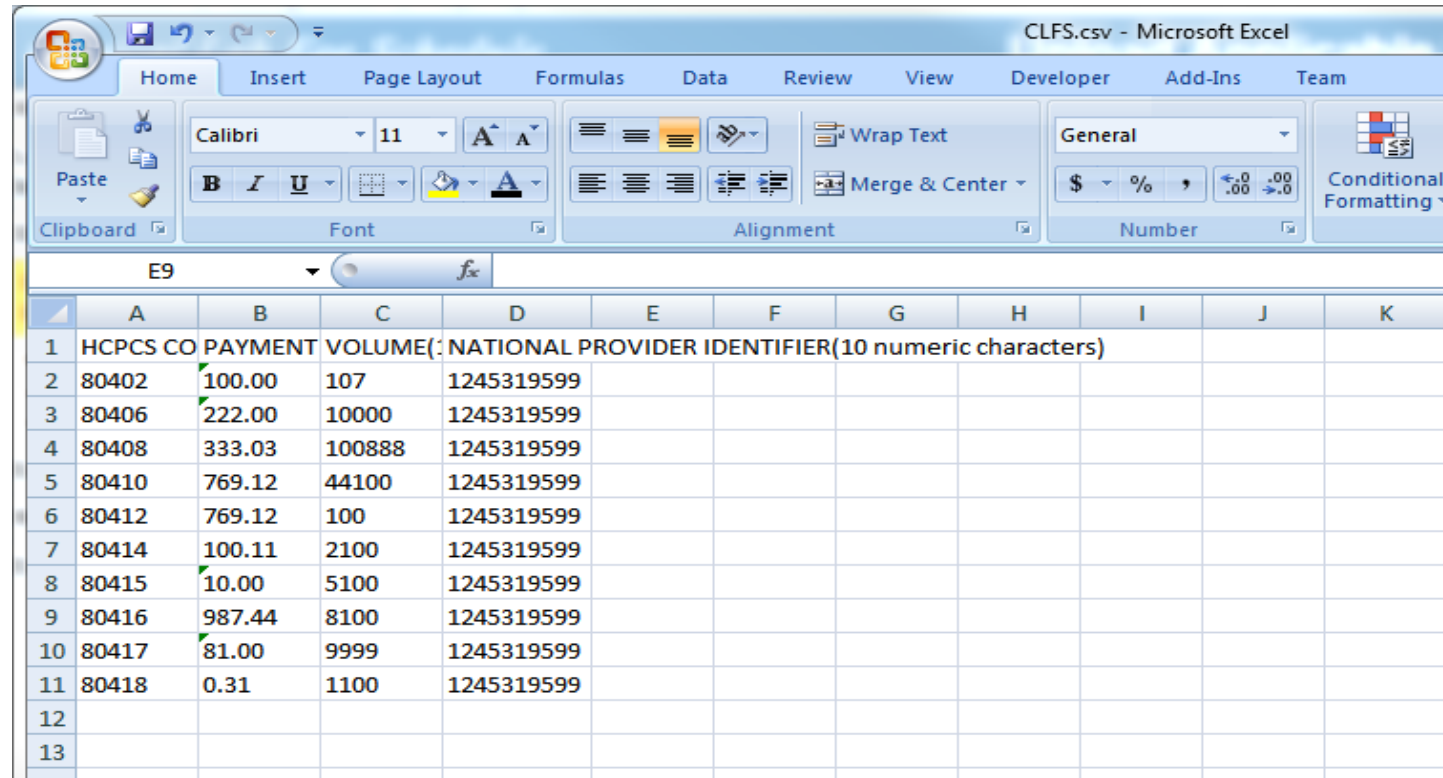
Applicable Information Submission Methods

- Option 1: Data upload
 - CLFS Data Reporting Template: [PAMA](#) Download
 - .csv file (i.e. upload via excel or text file)
 - Best option for laboratories submitting a large amount of data
- Option 2: Manual Entry
 - Best option for laboratories with only a few HCPCS codes to submit



Data Submission Option 1a:– Data Upload via MS Excel

All cells must be “text format”



CLFS.csv - Microsoft Excel

Home Insert Page Layout Formulas Data Review View Developer Add-Ins Team

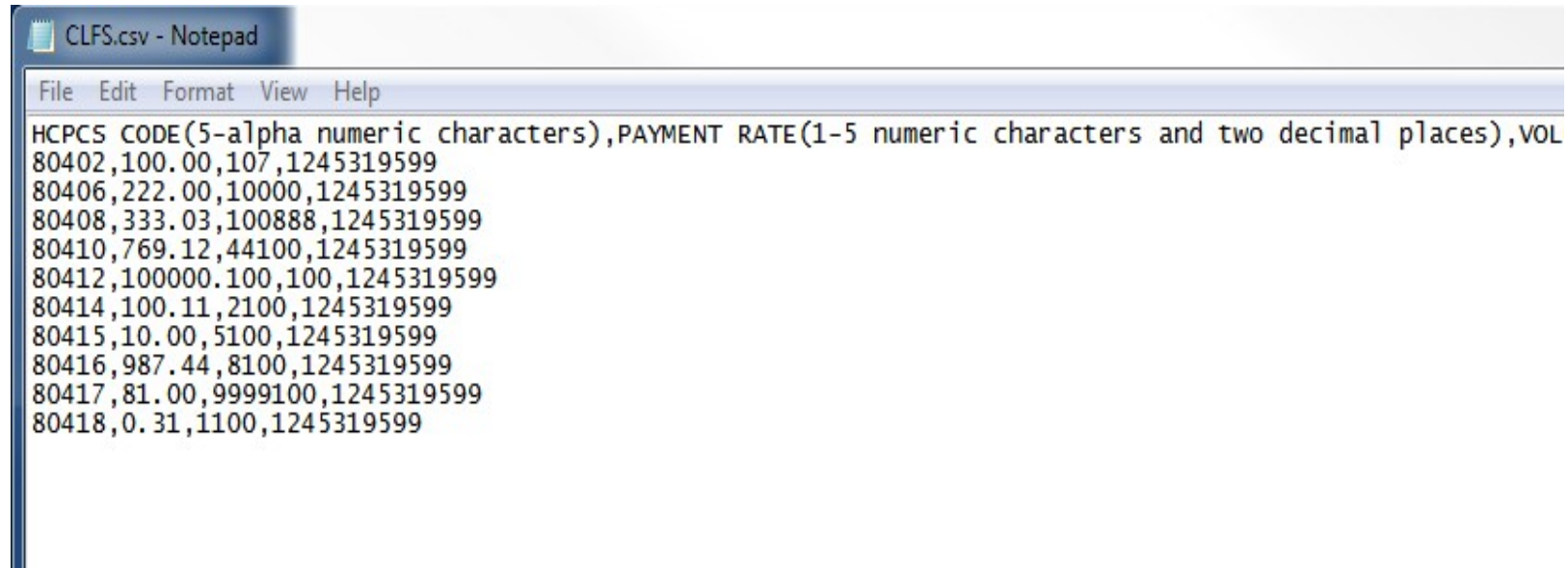
Paste Clipboard Font Alignment Number Conditional Formatting

E9

	A	B	C	D	E	F	G	H	I	J	K
1	HCPCS CO	PAYMENT	VOLUME(NATIONAL PROVIDER IDENTIFIER(10 numeric characters)							
2	80402	100.00	107	1245319599							
3	80406	222.00	10000	1245319599							
4	80408	333.03	100888	1245319599							
5	80410	769.12	44100	1245319599							
6	80412	769.12	100	1245319599							
7	80414	100.11	2100	1245319599							
8	80415	10.00	5100	1245319599							
9	80416	987.44	8100	1245319599							
10	80417	81.00	9999	1245319599							
11	80418	0.31	1100	1245319599							
12											
13											



Data Submission Option 1b: Data Upload via Text Editor



```
CLFS.csv - Notepad
File Edit Format View Help
HCPCS CODE(5-alpha numeric characters),PAYMENT RATE(1-5 numeric characters and two decimal places),VOL
80402,100.00,107,1245319599
80406,222.00,10000,1245319599
80408,333.03,100888,1245319599
80410,769.12,44100,1245319599
80412,100000.100,100,1245319599
80414,100.11,2100,1245319599
80415,10.00,5100,1245319599
80416,987.44,8100,1245319599
80417,81.00,9999100,1245319599
80418,0.31,1100,1245319599
```



System validates data post-upload

- System checks data for formatting errors
 - HCPCS codes (5 alphanumeric)
 - Payment Rate (2 decimal places)
 - Volume (no decimal places)
 - NPI (10 digits)
- Fix errors on screen and re-validate
- All lines should read “Validation check passed”
- Data is automatically saved when data passed validation

Clinical Lab Fee Schedule **Upload Applicable Information** [Help](#)

Home
Laboratory Information
Data Reporting
Upload Applicable Information
Manual Entry Applicable Information
Edit/View Data
Help
Exit

Current Reporting Period: 2016

Please use this data submission option if you have prepared all of your data in a .csv file that conforms to this [template](#). This is a good option if you want to upload a large amount of information at one time or use an automated data source.

[Refresh](#)

Last three uploaded files

File Name	Upload Type	Upload Date	Status
CLFS.csv	LAB DATA	2016-10-12 17:02:53.0	Completed
CLFS.csv	LAB DATA	2016-10-12 16:10:51.0	Completed
CLFS.csv	LAB DATA	2016-10-12 16:10:17.0	Completed

Lab Name: My Lab Name Lab TIN: 12-1212121 NPI: 1245319599-1811990831 CCN:

Please select file for data upload No file selected.
[Click here for acceptable file formats](#)

Step 4: Review and Save Data
Upload Date: 2016-10-12 17:02:53.0

Lab submission data not saved. Any records that have passed validation below are not saved until all records have passed validation. Please correct data.

Click on a field in the table header to sort in ascending order. Click again to sort in descending order.

HCPCS CODE	PAYMENT RATE	VOLUME	NPI	RESULT
80402	100.00	107	1245319599	Validation check passed.
80406	222.00	10000	1245319599	Validation check passed.
80408	333.03	100888	1245319599	Volume format 99999.
80410	769.12	44100	1245319599	Validation check passed.
80412	100000.100	100	1245319599	Payment Rate format 99999.99.
80414	100.11	2100	1245319599	Validation check passed.
80415	10.00	5100	1245319599	Validation check passed.
80416	987.44	8100	1245319599	Validation check passed.
80417	81.00	9999100	1245319599	Volume format 99999.



CLFS Data Submission Option 2 (Manual Entry)

- Key in data for each entry
- Save when complete

Clinical Lab Fee Schedule

Manual Entry Applicable Information

Help

Home

Laboratory Information

Data Reporting

Upload Applicable Information

Manual Entry Applicable Information

Edit/View Data

Help

Exit

Current Reporting Period: 2016

Please use this data submission option if you are submitting information on only a few tests or have minor additions to your uploaded data. If you have a large amount of information to submit, the File Upload data submission method may be a better option.

Lab Name: My Lab Name

Lab TIN: 12-1212121

NPI: 1811990831:1245319599

CCN:

Save Add More

ID	HCPCS CODE	PAYMENT RATE	VOLUME	NPI
1				
2				
3				
4				
5				

Save Add More



CLFS Data Corrections (Manual)

CLFS Submitter Role

Status

Validation

Corrections

[Clinical Lab Fee Schedule](#)

[Edit/View Data](#)

[Help](#)

[Home](#)

[Laboratory Information](#)

[Data Reporting](#)

[Edit/View Data](#)

[Help](#)

[Exit](#)

Current Reporting Period: 2016

HCPCS CODE:

Please use this data submission option if you are submitting information on only a few tests or have minor additions to your uploaded data. If you have a large amount of information to submit, the File Upload data submission method may be a better option.

Lab Name: My Lab Name

Lab TIN: 12-1212121

NPI: 1811990831:1245319599

CCN:

Click on a field in the table header to sort in ascending order. Click again to sort in descending order.

Showing all 7 results.					Previous First 1 Last Next	
ID	HCPCS CODE	PAYMENT RATE	VOLUME	NPI	Remove	
1	81545	10.00	100	1245319599	<input type="button" value="X"/>	
2	81545	10.00	200	1245319599	<input type="button" value="X"/>	
3	81545	10.00	300	1245319599	<input type="button" value="X"/>	
4	81545	10.00	400	1245319599	<input type="button" value="X"/>	
5	81545	10.00	500	1245319599	<input type="button" value="X"/>	
6	81545	10.00	600	1245319599	<input type="button" value="X"/>	
7	81545	10.00	700	1245319599	<input type="button" value="X"/>	

Showing all 7 results.

Previous First 1 Last Next



CLFS Data Certification - Registration

CLFS Certifier Role

- Registration

- Use One Time Password (OTP) from submitter

- Certification

Clinical Lab Fee Schedule **Laboratory Information** [Help](#)

Home
Laboratory Information
Data Reporting
Edit/View Data
Help
Exit

Laboratory Information

Generated OTP successfully. Expires 10/19/2016.

CLFS Registration Input

Username	Laboratory Name*	Tax Identification Number (TIN)	TIN type*	National Provider Identifier (NPI) Add Additional NPIs	CMS Certification Number (CCN) Add Additional CCNs
#	My Lab Name	12-1212121	EIN	1011590831	

[Save](#)

[Generate One Time Password](#)

All applicable information submitted by an applicable laboratory to CMS must be certified by either the President or CFO of the laboratory. Please click below to generate a one time password (OTP) and share this with the data certifier. Upon accessing the system to certify your laboratory's data, they will be asked for this password to verify their identity.

[Generate One Time Password \(OTP\)](#)

NnpgnlqwRxi6AOujFlgbWA

One Time Password expires on: 10/19/2016

[Next](#)

Clinical Lab Fee Schedule **Verify OTP** [Help](#)

Home
Verify OTP
Certification
Help
Exit

To certify and provide attestation for the data submitted, you must enter the tax identification number and one time password provided by your data submitter

[Laboratory Information](#)

Displays data from submitter's CLFS registration; Certifier must enter matching TIN in this table

Lab Name	Tax Identification Number (TIN)	TIN type	National Provider Identifier (NPI)	CMS Certification Number (CCN)
My Lab name	12-1212121	SELECT		

[One Time Password](#)

Enter OTP provided by your data submitter

NnpgnlqwRxi6AOujFlgbWA [Verify](#)

CLFS Data Certification

- CLFS Certifier Role
 - Registration
 - **Certification**

Clinical Lab Fee Schedule **Certification** [Help](#)

Home
Verify OTP
Certification
Help
Exit

Please select a reporting period: 2016

Lab Name: My Lab Name
Tax Identification Number (TIN): 12-1212121
National Provider Identifier (NPI): 1811990831:1245319599
CMS Certification Number (CCN):

HCPCS CODE	PAYMENT RATE	VOLUME	NPI	RESULT
81545	10.00	100	1245319599	SAVED
81545	10.00	200	1245319599	SAVED
81545	10.00	300	1245319599	SAVED
81545	10.00	400	1245319599	SAVED
81545	10.00	500	1245319599	SAVED
81545	10.00	600	1245319599	SAVED
81545	10.00	700	1245319599	SAVED
80402	100.00	107	1245319599	SAVED
80406	222.00	10000	1245319599	SAVED
80408	333.03	888	1245319599	SAVED
80410	769.12	44100	1245319599	SAVED
80412	769.12	100	1245319599	SAVED
80414	100.11	2100	1245319599	SAVED
80415	10.00	5100	1245319599	SAVED
80416	987.44	8100	1245319599	SAVED
80417	81.00	9999	1245319599	SAVED
80418	0.31	1100	1245319599	SAVED

Showing all 17 results. Previous First 1 Last Next



CLFS Data Certifier

- Cannot make edits to data
- If changes are necessary, certifier must inform Data Submitter
- Data Submitter must make any edits
- Once data are certified, they cannot be accessed by the laboratory



EIDM Registration

- Enterprise Identity Management
- Registration is open.
- Ready for data collection January 1, 2020.



CLFS Reference Material

On the [PAMA webpage](#):

- [CLFS Quick User Guide](#)
- CLFS User Guide
- [EIDM User Guide](#)
- [Data Template](#) (Excel)
- Contextual Help

CLFS helpdesk: clfshelpdesk@dcca.com
844-876-0765



Resources

- [PAMA](#) webpage
- Submit questions to CLFS_Inquiries@cms.hhs.gov



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