



# Increasing Metabolic Monitoring Operationalizing Point of Care Testing

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# Metabolic Monitoring

- Goals
  - Routinely screen for metabolic abnormalities in high risk populations
  - Monitor metabolic side effects of antipsychotic medication to inform medication treatment
  - Link individuals with metabolic abnormalities to medical care
- Alliance is increasing outcome measurement and moving toward value based payment; HEDIS measure outcomes will be a focus

# Metabolic Monitoring

- Point of care testing can improve outcomes by increasing Member access to monitoring and reducing communication barriers with labs
  - Diabetes screening for people with schizophrenia or bipolar disorder who are using antipsychotic medications
  - Metabolic monitoring for children and adolescents on antipsychotics

# Laboratory Requirements

- A CLIA certificate is required to conduct any test including POC fingerstick or urinalysis.
- Facilities doing only CLIA waived tests can certify under the CLIA Certificate of Waiver which requires:
  - Complete certificate of waiver every two years
  - Follow manufacturers instructions for each waived test
  - Notify State agency of organizational changes or addition of non-CLIA waived tests
  - Permit inspections by a CMS agent; there is no routine inspection schedule

# Laboratory Requirements

- A CLIA certificate is required for each testing site – mobile testing can be covered under a designated primary or home site
- There are no specified personnel requirements for CLIA waived tests

# Applying for CLIA Certificate of Waiver

- Apply for a CLIA certificate from CMS – Form 116 (waiver sections only)

<https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf>

- Submit certificate to state agency

State Agency contact info:

<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf>

# Applying for CLIA Certificate of Waiver

- Do not submit payment with the application; when application processed will receive a fee remittance coupon with the CLIA number

Fee Schedule:

[https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIA\\_certificate\\_fee\\_schedule.pdf](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIA_certificate_fee_schedule.pdf)

# CLIA Waived Tests and Billing

- Billing for POC testing is through NC Tracks; labs are billed as professional claims

Training:

<https://www.nctracks.nc.gov/content/public/providers/provider-user-guides-and-training.html>

Guides (Including Claims and Billing Guide):

<https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html>



# CLIA Waived Tests and Billing

- CMS lists waived tests, including approved device, and appropriate CPT code for billing  
[https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Categorization\\_of\\_Tests](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Categorization_of_Tests)
- NC Lab policy and Billing - Clinical Coverage Policy IS-3  
[https://files.nc.gov/ncdma/documents/files/1S-3\\_2.pdf](https://files.nc.gov/ncdma/documents/files/1S-3_2.pdf)

# CMS Resources

- CMS CLIA website:

[https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How\\_to\\_Apply\\_for\\_a\\_CLIA\\_Certificate\\_International\\_Laboratories](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How_to_Apply_for_a_CLIA_Certificate_International_Laboratories)

- CMS CLIA Brochures (explains requirements):

[https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA\\_Brochures](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures)

# CMS Resources

- CMS Brochure How to Obtain a CLIA Certificate of Waiver:

<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCertificateofWaiver.pdf>

# NC Resources

- NC Laboratory Services – includes links to clinical coverage policy, rate tables  
<https://medicaid.ncdhhs.gov/providers/programs-services/medical/laboratory-services>
- NC DHSR – CLIA section – regulates labs, oversees CLIA waived testing  
<https://info.ncdhhs.gov/dhsr/ahc/clia/index.html>
- NC DHSR – CLIA FAQs
- <https://info.ncdhhs.gov/dhsr/ahc/clia/cliafaq.html>