

CMS On-Site Inspection Checklist Pharmacy Compliance Program

Use this checklist when a CMS inspector arrives at your facility for a “no-notice” site inspection.

Inspection will occur within 45 days of a CMS-855S application submission to National Supplier Clearinghouse.

Recommendation: Place this checklist and the support documents listed below in the inside pocket of your Compliance Binder “A”.

Contact our office when a CMS inspector arrives at your facility and you need assistance 724-357-8380		
CMS Inspection Checklist Item	Location of items listed below is based on the R.J. Hedges Programs you are enrolled in	
	Location in Compliance Binder or Located Within Pharmacy	Location in Compliance Portal®/Compliance Program
Obtain copies of the following documents, if applicable: <ul style="list-style-type: none"> • Oxygen permit, if applicable • Pharmacy license • State DME permit, if applicable • Surety bond • Business liability insurance 	<ul style="list-style-type: none"> • Have current licensure and certification prominently displayed • Compliance Binder “A”; Professional Credentials tab • Compliance Binder “A”; Company Disclosures tab 	
Approximate size of the facility	<ul style="list-style-type: none"> • Determine the square footage of the facility (length x width = total square footage) • Posted in facility 	<ul style="list-style-type: none"> • Pharmacy: Chapter 11, OSHA; Item #1c, Floor Plan
Accessibility to physical site, including for the disabled	<ul style="list-style-type: none"> • Facility is open for business as posted on the door and as listed on the CMS Medicare Enrollment Application, CMS-855S Form 	
Hours of operation	<ul style="list-style-type: none"> • Hours posted at or on the front entrance 	<ul style="list-style-type: none"> • Pharmacy: Chapter 3, Pharmacy Operations; Item #1d-iii, “Customer Service Contact Information”
Provide a list of all management/owners with day to day control, including name and title	<ul style="list-style-type: none"> • Compliance Binder “A”; Company Disclosures tab 	<ul style="list-style-type: none"> • Pharmacy: Chapter 1, Corporate Structure and Governance; Item #2 and 2a, “Ownership Disclosure”
List of other locations	<ul style="list-style-type: none"> • If owner owns other facilities with a PTAN, provide a list of name(s), address(es) and PTAN(s) 	

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Patient records should include the following:	<ul style="list-style-type: none"> • Patient files for Part B Meds available for review 	<ul style="list-style-type: none"> • Blank documents
<ul style="list-style-type: none"> • Physician ordering/referral documentation 	<ul style="list-style-type: none"> • In patient billing records <ul style="list-style-type: none"> ○ 2019 and earlier: Detailed Written Order and/or Written Order Prior to Delivery ○ Effective January 1, 2020: Standard Written Order which is equivalent to the Treating Medical Practitioner’s written or ePrescribing prescription 	<ul style="list-style-type: none"> • Pharmacy: Chapter 3, Pharmacy Operations; Item #1e-i – vii, Detailed Written Orders and Written Orders Prior to Delivery
<ul style="list-style-type: none"> • Documentation of delivery 		<ul style="list-style-type: none"> • Pharmacy: Chapter 3, Pharmacy Operations; Item #1d-i, “Receipt of Goods and Services”
<ul style="list-style-type: none"> • Documentation of maintenance, repairs, or exchanges 	<ul style="list-style-type: none"> • Only available with DME program 	
<ul style="list-style-type: none"> • Proof of supplier provided equipment warranty 		<ul style="list-style-type: none"> • Pharmacy: Chapter 3, Pharmacy Operations; Item #1d-i, “Receipt of Goods and Services” third and fourth paragraphs
<ul style="list-style-type: none"> • Proof of supplier advice to beneficiary of option to rent or purchase inexpensive or routinely purchased equipment and of the capped rental policy 		<ul style="list-style-type: none"> • Pharmacy: Chapter 3, Pharmacy Operations; Item #1d-ii, “Capped Rental Service” • Pharmacy: Chapter 3, Pharmacy Operations; Item #1d-iv, “Terms and Conditions of Rental/Purchase Service Agreement”
<ul style="list-style-type: none"> • Proof that supplier provides beneficiary with written information and instruction on safe, effective use of Medicare covered items 	<ul style="list-style-type: none"> • User guide is either on or inside the DME container • Safety information • Operation/maintenance manual 	<ul style="list-style-type: none"> • Pharmacy: Chapter 3, Pharmacy Operations; Item #1d-i, “Receipt of Goods and Services” third paragraph

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	Location in Compliance Binder or Located Within Pharmacy	Location in Compliance Portal®/Compliance Program
Complaint policy & procedure and complaint log	<ul style="list-style-type: none"> Compliance Binder "B"; Quality Assurance and Performance Management tab 	<ul style="list-style-type: none"> Pharmacy: Chapter 7, Quality Assurance; Item #3, "Complaints to Covered Entity" Pharmacy: Chapter 7, Quality Assurance; Item #3a, "Patient Complaint Record" Pharmacy: Chapter 7, Quality Assurance; Item #3b, "Patient Complaint Log"
Business phone number	<ul style="list-style-type: none"> Copy of phone bill 	
Comprehensive liability insurance policy and/or the Certificate of Insurance showing NSC as the certificate holder with PO Box 100142, Columbia, SC 29202	<ul style="list-style-type: none"> Compliance Binder "A"; Company Disclosures tab 	
Required licenses, including zoning	<ul style="list-style-type: none"> Have current licensure and certification prominently displayed Compliance Binder "A"; Professional Credentials tab 	
Invoices and/or contracts to verify the purchase of Part B Meds NOTE: Must have signed agreements with vendors/wholesalers	<ul style="list-style-type: none"> Keep in front cover of HIPAA Binder 	<ul style="list-style-type: none"> Pharmacy: Chapter 3, Pharmacy Operations; Item #1d-i, "Receipt of Goods and Services" second paragraph
Service, maintenance, or replacement of DME items		<ul style="list-style-type: none"> Pharmacy: Chapter 3, Pharmacy Operations; Item #1d-iv, "Terms and Conditions of Rental/Purchase Service Agreement"

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Current supplier standards provided to all Medicare patients		<ul style="list-style-type: none"> Pharmacy: Chapter 3, Pharmacy Operations; Item #1d-i, "Receipt of Goods and Services" first paragraph
Contact information provided to beneficiary at time of delivery	<ul style="list-style-type: none"> Pharmacy label 	
Accreditation Information	<ul style="list-style-type: none"> Copy of the accreditation certificate Exempt pharmacies – copy of exemption document 	