



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES



May 19, 2006

Via Messenger

Herb Kuhn

Director Center for Medicare Management
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Quality Standards for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) in Relation to Regulation and Licensure of Pharmacies and Pharmacists and State Pharmacy Laws

Dear Mr. Kuhn:

The National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) appreciate the opportunity to provide further comments and information to the Centers for Medicare and Medicaid Services (CMS) on the Quality Standards for Suppliers of durable medical equipment, prosthetics, orthotics, supplies (DMEPOS) and accreditation of suppliers. In particular, we are providing information regarding their inapplicability to pharmacy providers in view of the comprehensive state pharmacy laws and licensure requirements for pharmacies and pharmacists. We agreed to provide CMS with this comparison of the quality standards in relation to state pharmacy laws. The comparison table is attached to this letter and a summary of the comparison is provided below. In addition, we have a document with all of the state pharmacy laws to support this comparison. If you would like to have a copy, please contact Diane Darvey at 703-837-4182 or ddarvey@nacds.org. We thank you for consideration of our comments.

General Comments

NACDS and NCPA and their members strongly believe that pharmacies and pharmacists have an important patient care role in assuring the appropriate use of DME products as well as prescription drugs and other health care items and services for Medicare beneficiaries, and that it is critical for Medicare beneficiaries to have access to these products and services in their community pharmacies. We also believe that the quality standards and accreditation requirements are unnecessary for community pharmacies in view of the extensive state pharmacy laws and the licensure through state boards of pharmacy.

Community retail pharmacies and pharmacists must comply with comprehensive state pharmacy laws in providing services to their patients, including professional and licensing requirements as a condition of operation.

Community retail pharmacies play a unique role in providing health care for Medicare beneficiaries. This includes providing non-service or cash and carry DME items such as diabetic supplies and other products, as well as dispensing prescription drugs to Medicare beneficiaries. In consideration of these factors, the existing comprehensive laws and regulations with which pharmacies have to comply, the state licensure of pharmacies and pharmacists, and pharmacists' extensive educational training, community pharmacies should not be faced with the same quality standards and accreditation requirements as DME suppliers that are not licensed health care professionals or those that provide more specialized DME products.

For these reasons, we ask that CMS determine that community retail pharmacies providing non-service DME items and related products and supplies be deemed exempt from the quality standards and accreditation. Our understanding is that Section 1834(a) (20) (A) of the Social Security Act, added by Section 302(a) (1) of the Medicare Modernization Act of 2003, provides the Secretary with this discretion. That provision requires the Secretary to "establish and implement quality standards for suppliers of items and services." However, it gives the Secretary authority to determine what items and services are covered "as the Secretary determines appropriate." Accordingly, we ask that this provision be used as means for the Secretary to deem that it is appropriate to exempt community pharmacies from the quality standards and accreditation provisions.

We further believe that the statute gives CMS considerable leeway in determining whether or not to apply these new standards to community pharmacies through accrediting organizations. For example, CMS has stated that it will be grandfathering in suppliers that have already been accredited by recognized accrediting organizations. Thus, CMS' consideration of "grandfathering" in certain entities indicates that it believes it can substitute CMS' criteria for these other standards. There is nothing in the statute or legislative history that would prevent CMS from adopting by reference another source of standards such as the state pharmacy laws and regulations. For example, there is nothing in the statute to prevent CMS from determining that the state pharmacy laws and regulations and licensure of community pharmacies and pharmacists will satisfy the quality standards for licensed community pharmacy DME suppliers.

The following is our summary of the comparison of the quality standards and pharmacy laws.

Comprehensive State Pharmacy Laws

Pharmacies and pharmacists in every state and U.S. territory are subject to stringent state laws and regulations that control the scope of pharmacy practice, required licensure and compliance standards. Accordingly, pharmacies and pharmacists providing DME products and services to their patients already meet different comprehensive standards than other non-licensed health care provider suppliers of DMEPOS items.

Pharmacy laws and regulations thoroughly and comprehensively regulate every aspect of the standards of pharmacy practice and the licensure of pharmacists and pharmacies. Before any pharmacy is permitted to operate and provide drugs, devices, services or supplies to patients, the pharmacy must meet rigorous standards of state licensure, including inspections and compliance with standards for pharmacy practice. As such, State Boards of Pharmacy regulate both the provision of products and the providing of professional services by pharmacies and pharmacists.

State laws set the scope of pharmacy practice for pharmacists. Pharmacies and pharmacists are subject to stringent professional practice standards that obviate the need for these additional quality standards. While the language of each state may differ, all states have laws that establish the scope of pharmacy practice including pharmacists' selection of drugs and devices, provision of patient counseling, professional responsibilities and other acts necessary to provide pharmacy patient care services such as consultation with prescribers about a patient's care and treatment.

Pharmacists Education and Training

State pharmacy laws and regulations establish the qualifications, training and experience requirements for pharmacists and pharmacy technicians including licensure, educational degrees, training, experience and continuing education for pharmacists for these individuals to be permitted to provide professional pharmacy services.

Pharmacists are highly educated to provide patients with counseling on proper use of drugs and medical devices and to provide counseling services. Pharmacists must graduate from an accredited pharmacy school and be licensed in the states where they practice pharmacy. All pharmacists are now required to graduate from a Doctor of Pharmacy degree program consisting of a minimum of 6 years of education with 2 years pre-pharmacy school and 4 years of pharmacy school. The pharmacists' educational program is extensive and includes clinical training directly with patients for advice on their care and training. After graduation from pharmacy school, pharmacists in all states must pass the National Association of Boards of Pharmacy Pharmacist Licensure Exam ("NAPLEX"). In addition, after graduation and passing the national exam, most graduates enter 1 or 2 year residency programs. In total, this represents at least six years of education and training and, in most instances, closer to eight years. All states require pharmacists to complete continuing education to maintain licensure, and usually this is 30 hours every two years.

Accordingly, today's pharmacist is uniquely qualified to serve as the medication and medical device use expert for advising and counseling Medicare patients and providing advice to other health care providers on the use of these health care products. Pharmacists are ideally situated to provide Medicare patients using non-service items such as diabetic supplies and other cash and carry items with counseling and important information on the proper use of these items. In addition, with the implementation of the Part D drug benefit, community pharmacies are where the majority of these patients will obtain their prescription drugs for diabetes and other health conditions. Such qualifications, education and training clearly differentiate pharmacists from general unlicensed retailers providing DME products, and should supplant application of the additional quality standards and accreditation to community pharmacies providing DME items and services.

Expecting national, regional or small chains – some with thousands of outlets – to seek accreditation for an important but small part of their business or to comply with the additional quality standards when they are already subject to comprehensive pharmacy law requirements is simply unrealistic. Accrediting agencies will face significant hurdles in accrediting all these pharmacies, and some pharmacies may believe that the cost of accreditation – both in time and resources – is too burdensome. This process could disrupt the important access that Medicare beneficiaries have had to items such as diabetic testing supplies and other health care items, and the critical coordination of receiving their prescription drugs for diabetes and other disease conditions from their community pharmacy.

State Laws Require Pharmacies to Have a Designated Pharmacist for Compliance

State pharmacy laws mandate that each pharmacy have a designated pharmacist who is responsible and accountable for the management and operation of that pharmacy and compliance with the laws and regulations. The state pharmacy laws, depending on the state, identify this pharmacist as the *pharmacist-in-charge (PIC)* or the *pharmacist manager* (hereafter referred to as the PIC). The PIC is responsible for pharmacies and pharmacists maintaining and providing proof of licensure in their pharmacies, and the pharmacy licensure requires a specific address and other information such as telephone number which would be available for beneficiary access.

State Pharmacy Laws Require Pharmacies to Have a Pharmacist on Duty

For Medicare beneficiaries, purchase of DME items in a community retail pharmacy provides the benefit of having a highly trained professional health care provider, the pharmacist, available to assist them. State pharmacy laws require pharmacies to have a pharmacist on duty when they are open for business and pharmacies must post their hours of operation. Community pharmacies are open early in the morning into the late evening and in many areas there is a 24 hour pharmacy available. When beneficiaries purchase their “over-the-counter” diabetic supplies and other cash and carry non-service items, the delivery occurs in the pharmacy with the pharmacist and the other pharmacy staff available to assist the beneficiary and answer any questions. Should any concerns or problems arise with the supplies, the beneficiaries are able to return them to the pharmacy. We believe that the most optimal service to Medicare beneficiaries with diabetes and other chronic disease conditions occurs as a result of regular interaction with the pharmacist in the local community pharmacy setting.

State Pharmacy Laws Establish Professional Conduct and Services for Pharmacists and Pharmacy Technicians

State pharmacy laws on professional conduct provide oversight for pharmacists’ services. Community retail pharmacies provide beneficiaries with an additional benefit of having a licensed pharmacist available to provide services to the beneficiary as needed and the oversight of the pharmacist-in-charge (PIC).

Community pharmacies are required by state pharmacy laws to maintain adequate operating hours. Moreover, an increasing number of community pharmacies are providing 24-hour services and a significant number remain open until the early evening hours. As a result, community pharmacies are very accessible to beneficiaries.

State pharmacy laws and regulations establish the qualifications, education and training, and examination requirements for pharmacy technicians to be permitted to work in a pharmacy. In most states, pharmacy technicians must be licensed or registered.

Pharmacists and pharmacy technicians are supervised by a pharmacist-in-charge or pharmacist manager who will require the pharmacy staff to adhere to applicable laws and regulations and pharmacy policies and procedures. This would include maintaining any required licensure or registration, competence and following policies and procedures.

Pharmacies are required by pharmacy laws and regulations to maintain complete records in computerized or hard copy for all prescriptions that are filled and refilled. The pharmacy records for prescription DME would be included in these requirements. Pharmacy laws and regulations also require pharmacies to keep hard copy records of new prescriptions and inventory records and invoices.

State Pharmacy Laws Require Pharmacists to Comply with Applicable Laws and Regulations

State laws and regulations require pharmacists to comply with all applicable laws and regulations including federal laws and regulations, to comply with the prescriber's instructions for filling prescriptions, and to consult with the prescriber for approval of any prescription changes. Pharmacists are required to document their communications and instructions from physicians and other health care providers for any clarifications or changes to prescription orders. State pharmacy laws and regulations would subject pharmacies and pharmacists to discipline for misrepresentations about their services. Pharmacists are not permitted to provide recalled products to patients. State pharmacy laws give the state boards of pharmacy authority to discipline pharmacists and pharmacies for improperly providing professional services to patients.

State laws and regulations require pharmacists to review and fully comply with the prescriber's instructions for filling all prescriptions including for any DME and to consult with the prescriber for approval of any prescription changes. Pharmacists are required to document their communications and instructions from physicians and other health care providers for any clarifications or changes to prescription orders. Pharmacists as licensed health care professionals comply with professional conduct standards that would require them to provide follow-up and referrals for their patients if they determined that was necessary for the patient's care and treatment.

Pharmacists are required to provide their patients with counseling on new prescriptions and if requested by the patient. For diabetic supplies and other non-service items, pharmacists would assist patients with training on how to use their diabetic testing supplies and other items upon request. In many states pharmacists engage in collaborative practice with physicians for certain patients, and in these instances additional patient education and training could be required pursuant to the protocol agreed upon between the physician and the pharmacy.

State pharmacy laws and regulations establish stringent requirements for pharmacy computer systems including maintenance of the information. These laws and regulations also establish requirements for maintenance of pharmacy records. Pharmacies' compliance with federal laws

and regulations for Medicare patients would include maintaining records for the time periods set under Medicare.

Pharmacies, pharmacists and other pharmacy staff are required to comply with HIPAA and the applicable state laws and regulations to maintain patient privacy and confidentiality of patient records.

Pharmacies and Pharmacists are Subject to Disciplinary Actions by Boards of Pharmacy

The pharmacy and pharmacist licensure laws establish the requirements for pharmacies and pharmacists including the disciplinary authority of the state boards of pharmacy. Pharmacies and pharmacists are subject to board of pharmacy disciplinary actions against their licenses for violations of laws and regulations.

Beneficiaries with comments about pharmacy services and pharmacist providers have the right to contact the state board of pharmacy. The state boards of pharmacy as consumer protection agencies are available to provide this service for patients. This consumer protection option does not exist with other non-licensed DME businesses that are not licensed pharmacies staffed with licensed pharmacists. Should problems with the monitors or other diabetic supplies arise they can be brought to the attention of the pharmacist. As appropriate depending on the non-service item such as diabetic supplies or other items, the pharmacist could bring this to the manufacturers' attention or assist the beneficiary in how to contact the manufacturer.

Pharmacists are Specifically Educated and Regulated to Work with Physicians in the Delivery of Care to Patients

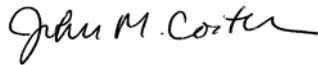
State pharmacy laws establish the scope of pharmacy practice, and require pharmacists to follow the instructions of the patient's physician including any treatment plan involving a prescription that comes within the pharmacist's scope of practice. Pharmacists' professional responsibilities would include providing the patient with products that follow the prescriber's prescription and have been provided by FDA approved manufacturers. This would include providing the patient with any needed information and pharmacist consultation on the use of the equipment and any needed supplies.

Summary and Recommendations

State-licensed community retail pharmacies should not be faced with the same quality standards and accreditation requirements as DME suppliers that are not licensed professional health care providers or those that provide more specialized DME products.

We respectfully ask that the Secretary determine pursuant to the statutory grant of authority under Section 1834(a) (20) (A) of the Social Security Act, added by Section 302(a) (1) of the Medicare Modernization Act of 2003, that community pharmacies providing non-service items are not covered by the quality standards and accreditation in consideration of the extensive and comprehensive state pharmacy laws, pharmacy and pharmacist licensure, pharmacist education and training, and the unique role of community pharmacies and pharmacists in providing care to Medicare beneficiaries.

Please direct any questions about these comments to NACDS' Diane Darvey at 703-837-4182 (ddarvey@nacds.org) or John Coster at 703-837-4126 (jcoster@nacds.org), or NCPA's William Popomaronis at 703-683-8200 (Bill.Popomaronis@ncpanet.org). Thank you for the opportunity to submit this information.



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cc: Linda Smith, RN, MSN, MBA

***CMS QUALITY STANDARDS for
SUPPLIERS OF DIABETIC EQUIPMENT AND SUPPLIES
Comparison with State Pharmacy Laws***

The following is a side-by-side comparison of the Quality Standards for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies and applicable pharmacy practice laws and regulations to provide information on their relative inapplicability to community retail pharmacists and pharmacy practice setting in view of the highly regulated pharmacy practice setting.

The following Appendices with copies of the state pharmacy laws for all 50 states are available upon request. Please contact Diane Darvey at 703-837-4182 or ddarvey@nacds.org.

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| Appendix A | Pharmacists Scope of Practice Laws |
| Appendix B | Board of Pharmacy Authority to Discipline |
| Appendix C | State Pharmacy Laws Pharmacist-in-Charge/Pharmacist Manager |
| Appendix D | State Pharmacy Laws for Pharmacist Professional Conduct |
| Appendix E | Examples of State Pharmacist Licensure Laws |

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| <i>Part 1. Supplier Business Quality Standards</i> | |
| <p><u>Administration</u></p> <p>1. Governing body or designated persons with legal authority, responsibility and accountability for establishing and implementing policies and procedures regarding the organization’s management and operation; and policies and procedures reviewed and revised annually to ensure they meet CMS regulations, policies and procedures and accreditation standards.</p> | <p><u>Administration</u></p> <p>1. State pharmacy laws and regulations require each retail pharmacy to have a designated person with legal authority, responsibility and accountability for the management and operation of the pharmacy. Depending on the state, this pharmacist is called the pharmacist-in-charge or pharmacist manager. (See Appendix C.)</p> <p>Each pharmacy has a pharmacist in charge. All pharmacies are required by the state board of pharmacy pursuant to state pharmacy laws and regulations to have a pharmacist-in-charge (PIC) for each pharmacy.</p> <p>Pharmacies usually must notify the board of pharmacy of the identity of the PIC for each</p> |

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| <p>2. Provide only equipment, supplies and services to Medicare beneficiaries disclosed on CMS-855S; and all licenses, certificates and permits to be displayed publicly and accessible on request to government officials</p> <p>3. Procurement and testing of quality DME and supplies – The supplier shall develop and implement policies and procedures that:</p> <ul style="list-style-type: none"> - Describe methods to ensure that manufacturers provide evidence of how equipment is tested to meets standards for quality and safety; at a minimum meet FDA medical device standards, ANSI, RESNA, ISO - Describe process for documentation of product’s features, instructions and warranties for each non-custom equipment. | <p>licensed pharmacy. The PIC is responsible for the practice of pharmacy including compliance with applicable federal and state laws and regulations.</p> <p>The PIC has responsibility for assuring that policies and procedures for all operations of the pharmacy are followed and for ensuring the pharmacy operations and practices comply with all applicable federal and state pharmacy laws and regulations.</p> <p>2. State pharmacy laws and regulations require that the PIC is responsible for the operation of the pharmacy including compliance with applicable laws and regulations and public display or proving proof of a permit or license as applicable. This would include compliance with applicable Medicare laws and regulations. (See Appendix C.)</p> <p>3. State pharmacy laws and regulations define the scope of pharmacy practice and require pharmacists to meet professional standards. (See Appendix A on pharmacists’ scope of practice, and Appendix D on pharmacists’ professional conduct.)</p> <p>Pharmacists and pharmacies could be subject to disciplinary actions for unprofessional conduct if they sold non-FDA approved products. Every state board of pharmacy has authority to issue disciplinary sanctions for engaging in misrepresentation in providing professional services or</p> |
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| <p>4. Delivery of services to beneficiaries The supplier shall be responsible for delivery of items to beneficiaries and maintain proof of delivery. The supplier shall develop and implement policies and procedures that:</p> <ul style="list-style-type: none"> • define scope of services, beneficiary eligibility, how services are coordinated with treating physician, health care team and business and emergency operating hours; • maintain business hours for minimum 40 hours a week • post business hours • have staff available for telephone customer service during posted business hours and after hours emergency services • ensure no mail order for initial delivery, set-up and beneficiary education, training for certain DME • For mail order replacements ensure that supplies are consistent with the treating physician and that qualified staff are available to respond to beneficiary concerns and needs. • Accept returns of substandard equipment • Describe procedures and timeframes for DME rental, delivery, pickup, maintenance, storage, repairs, replacement, warranties, costs and discharge of beneficiary from services • Ensure that in emergency supplier staff refers beneficiary to physician or 911 • Ensure that supplier maintain a list of all equipment and supplies and how they are provided to beneficiary and if covered by Medicaid or Medicare • Provides beneficiary with toll free number or | <p>professional activities. For OTC diabetic testing and supplies, the documentation of the product's features and warranties is included in the manufacturer's packaging that the patient takes home when with the purchase of the OTC diabetic testing items.</p> <p>4. For a beneficiary's purchase of over-the-counter (OTC) non-service items such as diabetic testing and supplies, the proof of delivery would be met when the patient purchases the diabetic supplies and is provided with a sales receipt that the patient maintains. In those instances, the beneficiary selects the product and there would be no delivery or pickup for repairs. The proof The manufacturer's product packaging would include product information for the purchaser on warranties and use of the product. In addition, pharmacists as health care professionals would provide the patient with any needed assistance and counseling on the use of the products including services for delivery, pick-up, repairs and service if the pharmacy provided DME requiring such services.</p> <p>State pharmacy laws and regulations on pharmacists' professional conduct and scope of practice would require pharmacies to take back defective products. (See Appendix A on scope of practice, and Appendix D on professional conduct.)</p> <p>In addition, state pharmacy laws</p> |
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| <p>national access number for all equipment</p> <p>5. Supplier shall comply with:</p> <ul style="list-style-type: none"> • Federal, state and local laws • Supplier enrollment standards at 42 CFR 424.57 • Disclosure of ownership and control information at 42 CFR 420.201, 42 CFR change of 424.204, 42 CFR 420.205 and 42 CFR 420.206 including written notice to CMS, National Supplier Clearinghouse (NSC), and its accreditation organization of change in officers, directors, agents or management, or corporation, association or other company responsible for the management, identity of each new individual or company and each supplier location shall meet the quality standards regulations and be accredited. • Other HHS regulations including nondiscrimination including but not limited to race, color, national origin, handicap and age, 45 CFR part 80, part 84, and part 91. | <p>and regulations require pharmacies to maintain adequate operating hours and to post the hours that the pharmacy is open.</p> <p>5. State pharmacy laws and regulations require each retail pharmacy to have a designated person with responsibility and accountability for the operation of the pharmacy including compliance with laws and regulations for the practice of pharmacy. Depending on the state, this pharmacist is called the pharmacist-in-charge or pharmacist manager. (See Appendix C.)</p> <p>Each pharmacy has a pharmacist in charge. All pharmacies are required by the state board of pharmacy pursuant to state pharmacy laws and regulations to have a pharmacist-in-charge (PIC) for each pharmacy.</p> <p>Each pharmacy must notify the board of pharmacy of the identity of the PIC for each licensed pharmacy.</p> <p>The PIC is responsible for overseeing compliance with all applicable laws and regulations.</p> <p>The PIC has responsibility for implementing policies and procedures for the practice of pharmacy and for ensuring the pharmacy practices comply with the requirements of federal and state pharmacy laws and regulations.</p> |
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| <p>6. Supplier shall develop and implement compliance plan to control fraud, waste, and abuse including:</p> <ul style="list-style-type: none"> • written policies and procedures and standards of conduct with all applicable federal and state standards • designation of compliance office and compliance committee or individuals accountable to senior management/ownership • effective training and education for the employees, contractors, agents and directors as applicable for compliance with standards • procedures to applying consistent enforcement of standards such as disciplinary guidelines • procedures for effective internal monitoring and auditing | <p>6. State pharmacy laws and regulations require each retail pharmacy to have a designated person with responsibility and accountability for the operation of the pharmacy. This would include compliance with federal and state Medicaid and Medicare provisions. (See Appendix C)</p> <p>Depending on the state, this pharmacist is called the pharmacist-in-charge or pharmacist manager. The PIC or pharmacist manager is accountable to the board of pharmacy and to the pharmacy owner for the practice of pharmacy and the pharmacists, pharmacy technicians, and other pharmacy staff while they are working in the pharmacy and in conjunction with the pharmacy permit holder for knowing that the pharmacy staff are properly licensed or registered as appropriate and trained as required by the state pharmacy laws and regulations.</p> <p>Relative to disciplinary proceedings, state boards of pharmacy have authority to discipline pharmacists and pharmacy technicians and pharmacies for unprofessional conduct or violations of laws and regulations. (See Appendix B on board of pharmacy disciplinary authority, and Appendix D on pharmacists' professional conduct.)</p> |
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| <p><u>Financial Management</u> Supplier shall:</p> <ul style="list-style-type: none"> • Develop and implement financial management policies, procedures and practices to ensure accurate accounting, business integrity and accountability • Use accounting system to track revenue and expenses • Provide evidence of the following to CMS, the accreditation organizations and others acting on behalf of the government upon request of: <ol style="list-style-type: none"> 1. Financial management plan with annual operating budget per GAAP, data sheet of annual projected and actual income, data sheet of annual expenses and cash flow, balance sheets, statements of changes in net position, invoices and receipts related to each beneficiaries equipment and supplies and services. 2. Financial statements that are accounted for, recorded and audited by accounting personnel to ensure financial propriety 3. Notice to CMS and accreditation organization of potential adverse financial operations. <ul style="list-style-type: none"> • The supplier shall maintain adequate financial resources to meet financial obligations for each quarter. • The supplier shall advise CMS and the supplier’s accrediting organization when it first becomes aware of adverse financial conditions which could result in delayed payments to manufacturers or suppliers or bankruptcy. | <p>Licensed pharmacies could not operate and be licensed in states without financial viability and to meet their professional conduct and pharmacy practice requirements. (See Appendix A and Appendix D.)</p> <p>They are required to be licensed as pharmacies and to maintain licensure through payment of initial and renewal licensure fees.</p> <p>If they have been found to have violated applicable laws and regulations, they would be required to pay fines and penalties.</p> <p>Pharmacies are also required to have other state and federal licenses including DEA registration, business licenses, and approval as state Medicaid providers.</p> |
| <p><u>Human Resource Management</u> Supplier shall:</p> <ul style="list-style-type: none"> • Develop and implement policies and procedures that specify personnel qualifications, training, experience and continuing education consistent with specialized equipment, supplies and services provided to beneficiaries • Obtain criminal background checks on all employees in compliance with federal and | <p>State pharmacy laws and regulations establish the qualifications, training and experience requirements for pharmacists and pharmacy technicians including licensure, educational degrees, training, experience and continuing education for pharmacists and pharmacy technicians for these</p> |

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| <p>state laws</p> <ul style="list-style-type: none"> • Have sufficient full time and part time personnel to meet beneficiary needs • Professional personnel shall be licensed, certified, registered per applicable state and federal laws and policies • Professional personnel shall be knowledgeable in equipment and supplies provided by the supplier for beneficiaries • Maintain documentation of annual verification of licensure, registrations, certifications and any other qualifications and competencies for its personnel and management involved in providing beneficiary services. • Have and implement assessment program to evaluate and document staff competence in areas related to its product specialization and beneficiary services • Have documentation that each staff member is current and in good standing with credentialing/licensure organizations. • Inform and train all management and staff on their responsibilities, types of services provided by the supplier, the policies and procedures and any other pertinent information. • Prohibit employees with a communicable disease or infected skin lesions from entering the home if could transmit disease, • Maintain current documentation on employees TB screening, Hepatitis B vaccination or decline per OSHA and CDC. • Ensure that all drivers who deliver to SNFs, hospitals, or any other entities have valid drivers license. • Ensure that personnel are employed and assigned responsibilities commensurate with their education and experience. • Credentialed individuals shall have documented knowledge and demonstrated competencies to <ul style="list-style-type: none"> - inspect, deliver and setup, evaluate, adjust and monitor the <u>prescribed</u> equipment - instruct the beneficiary and caregiver in the proper use, operation, maintenance, repair, | <p>individuals to be permitted to work in pharmacies. (See Appendix E.)</p> <p>In addition, pharmacists and pharmacy support staff are supervised by the onsite pharmacist-in-charge or pharmacist manager. (See Appendix C.) Many pharmacy owners do criminal background checks on individuals as part of the hiring process.</p> <p>Pharmacies, pharmacists, and pharmacy technicians are required to display their licenses, permits or registration cards in the pharmacies or with them to provide proof of current licensure, permit, or registration.</p> <p>Pharmacists must graduate from an accredited pharmacy school and be licensed in every state where they practice pharmacy. (See Appendix E.) All pharmacists are now required to graduate from a Doctor of Pharmacy degree program consisting of 6 years of education with 2 years pre-pharmacy school and 4 years of pharmacy school. The pharmacists educational programs are extensive and include clinical training to work with patients directly on their care and training. After graduation, the majority of pharmacy graduates then complete a one year residency program.</p> <p>All pharmacy graduates must be licensed to practice pharmacy in every state where they practice pharmacy. To obtain a pharmacy</p> |
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| <p>troubleshooting and reporting of problems for the equipment and</p> <ul style="list-style-type: none"> - communicate results of services to the treating physician and other health care team members | <p>license, each pharmacy school graduate must pass the national North American Pharmacists Licensure Exam (NAPLEX) and the Multistate Jurisprudence Exam (MJPE). In addition, each pharmacist must be licensed in each state where they practice. (See Appendix E.)</p> <p>States require that pharmacists maintain competency by completing a required number of continuing education hours during each license renewal period.</p> <p>State pharmacy laws and regulations establish the qualifications, education and training, and examination requirements for pharmacy technicians to be permitted to work in a pharmacy. In most states, pharmacy technicians must be licensed or registered.</p> <p>Pharmacists and pharmacy technicians are supervised by a pharmacist-in-charge or pharmacist manager who will require the pharmacy staff to adhere to applicable laws and regulations and pharmacy policies and procedures. This would include maintaining any required licensure or registration, competence and following policies and procedures. (See Appendix C.)</p> <p><i>Pharmacies Licensure Required</i> All pharmacies must be licensed by the state to provide pharmacy services. Their licenses must be maintained and must be posted.</p> |
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| <p><u>Beneficiary Services</u> Supplier shall</p> <p>1. Process and document physician orders in accord with instructions in the CMS Program Integrity Manual Ch 5.</p> <ul style="list-style-type: none"> • Document communication with physicians and other referral sources including review of prescription or referral and consultation with physician or referral source for clarification or modification • Consultation as necessary with other health care professionals and practitioners about the beneficiary's condition to formulate a service plan and document all finding and actions taken, and communicate this with appropriate health care professionals to ensure beneficiaries status is updated and current. <p>2. The supplier shall ensure the following when providing access to equipment, supplies, services and information for beneficiaries:</p> <ul style="list-style-type: none"> • In advertisement, websites and ordering instructions access to services is clearly explained • All DME and services include clear instructions on use, maintenance, potential hazards and how to report any failures and malfunctions. • There is a policy and process to remove recalled products from distribution, which includes parameters on how to notify beneficiaries and provide information on how to return or dispose of the product. • For DME suppliers, there are defined and guaranteed estimates for the time needed to ship items and they are disclosed to the beneficiary • Receipt of DMEPOS and services will be confirmed with the beneficiary and | <p>State laws and regulations require pharmacists to comply with all applicable laws and regulations (which would include CMS requirements) and to fully comply with the prescriber's instructions for filling all prescriptions and to consult with the prescriber for approval of any prescription changes. (See Appendix A on scope of pharmacy practice, Appendix C on the pharmacist in charge, and Appendix D on pharmacists' professional conduct.)</p> <p>Pharmacists are required to document their communications and instructions from physicians and other health care providers for any clarifications or changes to prescription orders.</p> <p>2. State pharmacy laws and regulations would subject pharmacies and pharmacists to discipline for misrepresentations about their services. Pharmacists are not permitted to provide recalled products to patients. (See Appendix B on board of pharmacy disciplinary authority, and Appendix D on pharmacists' professional conduct.)</p> <p>Many of the requirements in this section are inapplicable to OTC items typically supplied by retail pharmacies that are selected and purchased by the patient as such products would not be shipped or rented.</p> |
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| <ul style="list-style-type: none"> • For DME, suppliers shall have identification stickers on capped rental equipment showing the company's name, address and tel. number. <p>3. Supplier shall ensure coordination of services with the treating physician and other healthcare team and shall:</p> <ul style="list-style-type: none"> • Review all physician orders to ensure clear understanding of equipment and supplies requested and shall use this in the delivery planning process • Consider the beneficiary or caregiver's needs when scheduling delivery • Consult with the treating physician and healthcare team to obtain pertinent beneficiary health care information that may impact medical use of the prescribed equipment i.e. diagnosis, prognosis, mental status, functional limitations, types of services and equipment required, amount, frequency and duration of treatments, frequency of visits, rehabilitation potential, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge and or referral, and any other necessary information for delivery of appropriate services. <p>4. The supplier shall develop and implement policies and procedures describing:</p> <ul style="list-style-type: none"> • The referral and acceptance process • How delivery of equipment and services are prioritized and • Staff response during emergencies, inclement weather, or any other emergent event that may disrupt services. <p>5. The supplier shall ensure that education and training is provided to the beneficiary on how to</p> | <p>3. State laws and regulations require pharmacists to review and fully comply with the prescriber's instructions for filling all prescriptions including for any DME and to consult with the prescriber for approval of any prescription changes. (See Appendix A on scope of pharmacy practice.)</p> <p>Pharmacists are required to document their communications and instructions from physicians and other health care providers for any clarifications or changes to prescription orders.</p> <p>4. Pharmacists as licensed health care professionals comply with professional conduct standards that would require them to provide follow-up and referrals for their patients if they determined that was necessary for the patient's care and treatment. (See Appendix A on pharmacists' scope of practice.)</p> <p>5. Pharmacists are required to provide their patients with</p> |
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| <p>use Medicare covered items safely and effectively. This education and training shall be Documented in the beneficiary's service plan including identification of those who conducted the training. Evidence that the beneficiary or caregiver demonstrated their understanding of instructions shall be documented in the service plan.</p> | <p>counseling on new prescriptions and if requested by the patient. For OTC items, pharmacists would assist patients with training on how to use their non-service items and supplies upon request. In many states pharmacists engage in collaborative practice with physicians for certain patients, and in these instances additional patient education and training could be required pursuant to the protocol agreed upon between the physician and the pharmacy. (See Appendix A on pharmacists' scope of practice.) In addition, state pharmacy laws and regulations have comprehensive provisions governing pharmacists' counseling of patients.</p> |
| <p><u>Performance Management</u> The supplier shall develop and implement a performance management system that measures its effectiveness and efficiency in meeting goals, compliance with policies and procedures and with federal, state and local law requirements, and compare projected to actual results, investigate deviations from plans, evaluate individual staff performances, examine progress to meeting objectives and implement corrective actions.</p> <ol style="list-style-type: none"> 1. Provide evidence of performance criteria monitored and evaluated, and outcomes and actions taken and include quantitative and qualitative measures. 2. Identify, monitor and evaluate problems to determine root causes including any adverse effects of equipment and supplies 3. Respond to identified problems by developing, implementing and monitoring strategies to improve quality of services and products. 4. Implement procedures and a schedule to evaluate the effectiveness of strategies | <p><u>Performance Management</u> The pharmacy and pharmacist licensure standards and professional standards impose stricter requirements on pharmacies and pharmacists than a performance system. Pharmacies and pharmacists would be subject to board of pharmacy actions against their licenses for violations of laws and regulations and improper patient care. (See Appendix E on pharmacist licensure and Appendix B on board of pharmacy disciplinary authority.)</p> <p>Beneficiaries with complaints about pharmacy services and pharmacist providers have the right to complain to the state board of pharmacy. The state boards of pharmacy are consumer protection agencies. This</p> |

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| <p>used.</p> <p>5. Conduct beneficiary satisfaction surveys and make results available on request and/or listed on website if applicable, and document and review quarterly percentage of beneficiaries satisfied with services.</p> <p>6. Performance management system shall use mechanisms to track trends and patterns related to quality and outcomes of service, staff performance, beneficiary satisfactions, and financial stability of the organization such as:</p> <p><i>Reported as percentages</i></p> <ul style="list-style-type: none"> - accuracy of bills submitted to Medicare - accuracy of bills submitted to beneficiaries - beneficiary complaints - complaints resolved to all complaints - beneficiary complaints used to improve organizational performance - responses to beneficiaries within 60 minutes - beneficiary calls with questions on equipment or supplies after provision of education and training - distribution errors - product returns re all products shipped - product failures - product recalls re all products shipped - staff that achieve competency in annual assessments <p><i>Reported as a number</i></p> <ul style="list-style-type: none"> - number of adverse effect on beneficiaries as a result of inadequate or malfunctioning equipment, supplies, or services e.g. actual or potential cause or contribution to a death or serious injury to the beneficiary as a result of malfunctioning equipment or services. | <p>consumer protection option does not exist with non-licensed DME businesses that do not use licensed pharmacists and pharmacies.</p> |
| <p><u>Equipment and Safety</u> The supplier shall develop and implement equipment management program that ensures the prevention and control of safety risks and hazards both for its staff and for beneficiaries.</p> <p>1. The supplier shall maintain a current and accurate inventory of all equipment</p> | <p><u>Equipment and Safety</u> Pharmacists as licensed by the state boards of pharmacy would be required to comply with state laws and regulations including those applicable to warranties and recall notices relative to the recall</p> |

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| <p>including model, stock number, serial number, batch number, expiration date and other information as applicable.</p> <ol style="list-style-type: none"> 2. The DME supplier shall implement and maintain a system for tracking and monitoring the history of all equipment including an item's functions, failures, recalls, repairs, preventive maintenance, inspection, testing and calibrations; have a policy and process to report product failures to manufacturers and to appropriate agencies. 3. The DME supplier shall implement a system that describes how equipment will be serviced and routine follow-up procedures as well as emergency response procedures to prevent any interruption of services to beneficiaries. 4. The supplier shall implement and maintain a process for honoring all warranties express and implied under applicable State laws; shall not charge the beneficiary or Medicare for the repair or replacement of items or for services covered under warranty. This applies to all purchased and rented items, including capped rental items 42 CFR 414.229. Supplier shall maintain documentation that it has provided beneficiaries with information about Medicare supplied items covered under warranty in form of letters, logs or signed notices. 5. The supplier shall conduct an environmental safety evaluation of a beneficiary's home including emergency power and notify the treating physician of potential or actual problems that may interfere with effective functioning or usage of the beneficiary's equipment (not applicable to O&P). 6. The supplier shall comply with all federal, state and local laws and instructions regarding safe transportation, storage, use, generation, and labeling of hazardous chemicals, materials, and waste including cytotoxic medications, | <p>of defective products and would follow the manufacturer's and the Food and Drug Administration's instructions on product recalls. (See Appendix E on pharmacist licensure.)</p> <p>Pharmacists would also be subject to state public health and safety laws that could prohibit pharmacies from taking back opened and used items and supplies due to public health and safety risks.</p> <p>The PIC is responsible for overseeing compliance with all applicable laws and regulations. (See Appendix C.)</p> <p>The pharmacist-in-charge or pharmacist-manager would have responsibility for requiring compliance with policies and procedures for all operations of the pharmacy and for ensuring the pharmacy practices comply with requirements of federal and state pharmacy laws and regulations including those for the safe storage, use and labeling of hazardous chemicals, materials, cytotoxic agents, and parenteral and enteral nutrition solutions. .</p> <p>The requirement for the supplier to conduct an environmental safety evaluation of the beneficiary's home would not be applicable to non-service items cash and carry items and supplies that the beneficiary purchases at a retail pharmacy and takes home for personal use.</p> <p>The state boards of pharmacy that</p> |
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| <p>medical gases, blood and blood soaked items.</p> <ol style="list-style-type: none"> 7. The supplier shall ensure there is adequate space within its facilities to support the delivery of beneficiary services as well as separation of the manufacturing or storage of equipment from any hazardous materials and waste. 8. The supplier shall implement policies and procedures for the proper storage of parenteral and enteral nutrition therapy solutions and formulas, and medications with appropriate sanitation, temperature, light, moisture, ventilation, segregation, safety, and security (does not apply to O&P facilities). 9. The supplier shall implement policies and procedures regarding the preparation of medications and parenteral and enteral nutrition therapy solutions. | <p>issue pharmacy licenses and permits establish the requirements for pharmacy layout and physical requirements and perform inspections before the license or permit is issued. Pharmacies are required to have proper equipment and references for pharmacist provided services.</p> <p>For OTC non-service items and supplies that are selected and purchased by patients and taken home for personal use, the products would not be used by pharmacy staff because they are taken home by the purchaser for personal use and not returned to the pharmacy. Additionally, because the patient has purchased the product for self-use, they would be serviced by the manufacturer if service is needed. In the event of a product recall, pharmacists would follow FDA recall instructions.</p> |
| <p><u>Beneficiary Rights and Ethics</u></p> <p>The beneficiary has a right to self-determination as well as access to and communication with persons and services of the supplier and healthcare team.</p> <p>A supplier shall protect and promote the rights of each beneficiary.</p> <ol style="list-style-type: none"> 1. Prior to furnishing equipment, supplies, or services, the supplier shall inform the beneficiary of the following: <ul style="list-style-type: none"> • Products and services that will be furnished • Any changes in products and services • Schedule and procedures staff will follow to provide the products and services including frequency of proposed visits | <p><u>Beneficiary Rights and Ethics</u></p> <p>Pharmacists are required to provide their patients with counseling on new prescriptions and if requested by the patient. For OTC non-service items, pharmacists would assist patients with training on how to use their diabetic testing and supplies upon request. In many states pharmacists engage in collaborative practice with physicians for certain patients, and in these instances additional patient education and training could be required pursuant to the</p> |

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| <ul style="list-style-type: none"> • The rental versus purchase options available for equipment and supplies including associated costs (not applicable to O&P) • Policies for after-hours and emergency coverage; and • Telephone numbers for repair, emergencies and customer service assistance <p>2. The supplier shall respect the need of beneficiaries for confidentiality, privacy, and security. The supplier shall:</p> <ul style="list-style-type: none"> • Respect the beneficiary’s right to personal privacy during rendering of services and • Respect the beneficiary’s personal property and security during home visits <p>3. The beneficiary has the right to request and to have the supplier resolve oral, written, and telephone complaints concerning the products and services provided by the supplier. The supplier shall develop and implement a complaint resolution system for identifying, responding to, and resolving complaints. The supplier shall maintain documentation of all written, oral, and telephone complaints it receives including:</p> <ul style="list-style-type: none"> • The name, address and telephone number of the beneficiary • A summary of the complaint including date received, name of person making the complaint, the name of the person receiving the complaint, and a summary of the actions taken to resolve the complaint • If an investigation was not conducted, the name of the person making the decision not to investigate and the reason for not doing so. | <p>protocol agreed upon between the physician and the pharmacy. (See Appendix A on scope of pharmacy practice.)</p> <p>Pharmacists as licensed health care professionals would comply with state pharmacy laws and regulations for proper storage of drugs and medical equipment and devices including parenteral and enteral solutions. (See Appendix A on scope of pharmacy practice, Appendix D on professional conduct, and Appendix E on pharmacist licensure.)</p> <p>Relative to patient privacy and confidentiality, pharmacies are subject to state and federal patient privacy and confidentiality laws including HIPAA in how they handle, process and store patient’s protected health information.</p> <p>Pharmacies routinely handle requests from their patients about the pharmacy products and services that they purchase. If appropriate, pharmacists would assist patients with how to reach the manufacturer of the products.</p> |
| <p><u>Information Management</u> The supplier shall develop and implement an information management system that ensures the accuracy, accessibility, confidentiality, and security of the organization’s beneficiary’s records, data, and dissemination of information.</p> | <p><u>Information Management</u> Pharmacies are one of the most highly computerized segments of health care. Pharmacies have been computerized for several decades with increasingly</p> |

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| <p>The supplier shall comply with the appropriate provisions and requirements of HIPAA and other applicable federal and state requirements.</p> <ol style="list-style-type: none"> 1. The supplier shall maintain records on each beneficiary that are complete, accurate, readily accessible, and systematically organized. A beneficiary's record shall include detailed descriptions of the specific products used by the beneficiary, customized designs of appliances and devices in use, pertinent medical history, relevant financial records, services provided including any follow-up, and evidence of any beneficiary education and training regarding DMEPOS and other items and services. 2. For suppliers that maintain records by computer instead of hard copy, the supplier shall develop and implement policies and procedures for electronic signatures and describe the attestation policy(ies) for electronic signatures and other safeguards in force at each supplier location. In cases where such attestation is done on computer records, safeguards to prevent unauthorized access and reconstruction of information shall be in place including at | <p>advanced systems that provide for the accuracy and security of pharmacy patient records. Each state has laws and regulations establishing requirements for computer and hardcopy pharmacy records including that they be maintained for a specified number of years and be readily accessible to the state board of pharmacy.</p> <p>Relative to patient privacy and confidentiality, pharmacies are subject to state and federal patient privacy and confidentiality laws including HIPAA in how they handle, process and store patient's protected health information. Some of these requirements would not be applicable to purchase of cash and carry non-service items.</p> <ol style="list-style-type: none"> 1. Pharmacies are required by pharmacy laws and regulations to maintain complete records computerized and/or hard copy for all prescriptions that are filled and refilled. The pharmacy records for prescribed DME would be included in these requirements. 2. Pharmacy laws and regulations also require pharmacies to keep hard copy records of new prescriptions and inventory records and invoices. Many state laws allow pharmacies to maintain prescription records electronically either as a scanned image of the prescription or via an electronic prescription. |
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| <p>minimum:</p> <ul style="list-style-type: none"> • Each computer or network shall have built-in safeguards to minimize the possibility of fraud; • Each person responsible for an attestation has a unique individual identifier; • The date and time is recorded from the computer's internal clock at the time of an entry, and date/time stamping is maintained to be accurate and current; • An entry is not to be changed after it has been recorded; • There is a backup system for all records and a process in place to provide for disaster recovery and business continuity; and • Information systems and computer servers are secure. <p>3. The supplier shall implement safeguards to prevent loss, tampering, alternation, destruction, and unauthorized use or inadvertent disclosure of information and beneficiary records.</p> <p>4. The supplier shall develop, implement, and enforce policies to prevent falsification of data and information.</p> | <p>Pharmacies have used computerized systems for many years and have highly developed systems that provide safeguards, audit logs and back up requirements.</p> <p>State pharmacy laws and regulations establish stringent requirements for pharmacy computer systems including maintenance of the information. These laws and regulations also require that pharmacy records be maintained for at least two years and many states require records to be maintained for three years or longer.</p> <p>Pharmacies compliance with federal laws and regulations for Medicare patients would include maintaining records for the time periods set under Medicare.</p> <p>3. Pharmacies, pharmacists and other pharmacy staff are required to comply with HIPAA and the applicable state laws and regulations to maintain patient privacy and confidentiality of patient records.</p> <p>4. State pharmacy laws and regulations as well as federal and state Medicare and Medicaid laws and regulations require that pharmacy patient records be accurate. In addition, pharmacies and pharmacists as licensed by state boards of pharmacy are subject to discipline for violation of laws. (See Appendix B on board of pharmacy disciplinary</p> |
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| <p>5. The supplier shall develop and implement procedures governing the use and removal of records and the conditions for release of information.</p> <p>6. The supplier shall implement a system to collect and aggregate administrative and beneficiary service data to ensure accuracy of interpretation, and to support decision-making, business operations, and performance improvement.</p> <p>7. The supplier shall retain records of each beneficiary's equipment, supplies, education/training, and complaints for five years.</p> <p>8. The supplier's marketing materials shall be clear, factual and not misrepresent the educational intent or Medicare costs and requirements for its products and supplies. The supplier's materials and websites (if applicable) provide:</p> <ul style="list-style-type: none"> • Documentation of accreditation, licensure and/or certification • Information for direct beneficiary access to a certified/licensed person, as | <p>authority.)</p> <p>5. Pharmacies, pharmacists and other pharmacy staff are required to comply with HIPAA and the applicable state laws and regulations to maintain patient privacy and confidentiality of patient records.</p> <p>6. State pharmacy laws and regulations establish requirements for pharmacy computer systems including maintenance and accuracy of the information which would include information on prescriptions for Medicare beneficiaries. These laws and regulations also require that pharmacy records be maintained.</p> <p>7. State pharmacy laws and regulations establish requirements for pharmacy computer systems including maintenance and accuracy of the information which would include information on prescriptions for Medicare beneficiaries. These laws and regulations also require that pharmacy records be maintained and allow pharmacies to maintain electronic or paper records.</p> <p>8. Licensed pharmacies and pharmacists are subject to state laws and regulations prohibiting unprofessional conduct. and are required to comply with state laws and regulations regarding unfair or deceptive trade practices. (See Appendix D on pharmacists' professional conduct and Appendix B on board of</p> |
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| <p>applicable;</p> <ul style="list-style-type: none"> • A toll-free telephone number for direct beneficiary communication to DMEPOS service staff; • The location and address of the DMEPOS supplier; and • Forms for beneficiaries to download that are easy to access and use. | <p>pharmacy disciplinary authority.)</p> <p>In addition, the PIC is responsible for pharmacies and pharmacists maintaining and providing proof of licensure in their pharmacies, and the pharmacy licensure requires a specific address and other information such as telephone number which would be available for beneficiary access.</p> <p>In addition, state pharmacy laws and regulations require that prescription labels include the pharmacy address and telephone number.</p> |
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APPENDIX H: DIABETIC EQUIPMENT AND SUPPLIES

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| <p><i>Inspection And Preparation</i></p> | |
| <p><u>General Product Specific Requirements</u> The supplier shall ensure that the equipment is safe and fully functional, and adjust, repair, or replace parts if the condition of a product is below factory new-equivalent performance, or defects would render equipment unsafe. If adjustment, repair, or replacement of parts is not feasible or not sufficient to make the equipment safe and functional, the equipment shall be replaced.</p> <p><u>Intake</u> General Product Specific Requirements The supplier shall:</p> <ul style="list-style-type: none"> • Obtain a written prescription from the Medicare beneficiary’s treating physician for the equipment; • Consult wit the treating physician as needed, to confirm the prescription and to recommend any changes or refinements to the prescribed regimen; and | <p>State pharmacy laws and regulations require pharmacies to have prescriptions if a drug or device is prescription only. In addition, state pharmacy laws and regulations establish the scope of pharmacy practice, and require pharmacists to consult with the patient’s physician as needed for any changes or refinements to a patient’s prescription and to follow any treatment plan of the patient’s physician which would include providing a home blood glucose monitor appropriate for the patient as ordered by the patient’s physician. (See Appendix A, on Pharmacists’ Scope of Practice Laws)</p> <p>Pharmacist professional patient</p> |

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| <ul style="list-style-type: none"> • Assure that the prescribed equipment is appropriate for the medical needs of the beneficiary. • Ensure changes in equipment and services are accepted by the treating physician via either verbal or written communication. The supplier shall ensure that only individuals who are authorized under applicable state laws and regulations accept verbal orders. A written order from the treating physician shall be on file upon billing for delivered services. <p><u>Service Plan</u> General Product Specific Requirements The supplier shall:</p> <ul style="list-style-type: none"> • Develop and implement a service plan for each beneficiary based on the treating physician’s plan of care; and • Periodically review the service plan and incorporate any necessary revisions. The treating physician shall be contacted to discuss: <ul style="list-style-type: none"> ○ Changes in the beneficiary’s clinical condition; ○ Proposed changes in the service plan that affect the prescribed equipment or services; and ○ Identification of new beneficiary problems and needs or recurrence of previously resolved problems and needs. <p><u>Equipment Management</u> General Product Specific Requirements The supplier shall</p> <ul style="list-style-type: none"> • Inspect the equipment to ensure that all necessary components are present; • Check that the equipment is consistent with the treating physician’s prescription and any other criteria for use; and • Adjust, repair, or replace all components to ensure that they do not pose a hazard or usage problem for the beneficiary. | <p>services are patient-centered and include patient counseling and assistance so that the patient has the supplies and information necessary for the treatment plan.</p> <p>Diabetic supplies generally do not require a prescription. However, in the event that a prescription is required, pharmacies compliance with the applicable state pharmacy laws should be considered compliance with these standards.</p> <p>State pharmacy laws and regulations require pharmacists to follow the prescription of the prescriber for the patient’s care and treatment. (See Appendix A)</p> <p>Pharmacists as part of their professional responsibilities would be required to provide properly inspected equipment and to provide equipment that follows the prescriber’s prescription. (See Appendix A scope of pharmacy practice and Appendix D on professional conduct.)</p> <p>As discussed above for service plans, pharmacists’ professional responsibilities would include providing the patient with products that follow the prescriber’s prescription and have been provided by FDA approved manufacturers. (See Appendix A scope of pharmacy practice and Appendix D on professional</p> |
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| <p>In addition to General Product Specific Requirements</p> <ul style="list-style-type: none"> - Supplier shall furnish a home blood glucose monitor that is appropriate for any physical limitations such as visual impairment. | <p>conduct.)</p> |
| <p>Delivery/Setup</p> <p>General Product Specific Requirements</p> <p>The supplier shall ensure the equipment is properly delivered, setup and fully functional.</p> <p>The supplier shall:</p> <ul style="list-style-type: none"> • Obtain physician orders for all necessary equipment, supplies and accessories; • Deliver and set up, or coordinate set up with a clinician or another provider, all equipment and supplies in a timely manner as agreed upon by the beneficiary and/or caregiver and supplier; • Provide all supplies necessary to operate the equipment and that are needed along with the equipment; • Ensure that instructions on the operation, safety, maintenance, repair, and replacement are provided to the beneficiary along with any warnings about use, and any additional manufacturer's instructions; • Ensure that all equipment and supplies are clean and sterile as indicated; • Take reasonable measures to present instructions and information to the beneficiary and/or caregiver in clear, understandable language; • Supply any follow-up service; • Assess and reassess parameters for the specific equipment and/or any physician guidelines. • Perform or arrange for any needed maintenance and repairs or replacement; • Have access to replacement parts, either through maintaining inventory or arrangements with other suppliers; • Provide a written estimate to the beneficiary of the cost and time required for any repair work; • Provide, or arrange for, loaner equipment | <p>State pharmacy laws and regulations require pharmacists to follow the instructions of the patient's physician including any changes or refinements to a patient's prescription and to follow any treatment plan of the patient's physician. This would include providing the patient with any needed information and pharmacist consultation on the use of the equipment and any needed supplies. Pharmacy laws and regulations as well as pharmacists' professional standards require pharmacists to provide patient consultation and information required for the use of equipment and supplies. (See, Appendix A, Pharmacists Scope of Pharmacy Practice Laws.)</p> <p>Each pharmacy has a pharmacist in charge or pharmacist manager. All pharmacies are required by the state board of pharmacy pursuant to state pharmacy laws and regulations to have a pharmacist-in-charge (PIC) or pharmacist manager that would oversee the practice of pharmacy which would include services to Medicare beneficiaries. (See Appendix C for state laws for pharmacists in charge or pharmacist managers.)</p> <p>The pharmacist's professional responsibilities and following the prescription instruction would</p> |

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| <p>comparable to the original equipment for any repair period;</p> <ul style="list-style-type: none"> • Establish an adequate means for the beneficiary to communicate needs and desires and to obtain help in case of emergency; • Advise the beneficiary on how to communicate their needs and concerns and to summon help in case of an emergency; • Document the beneficiary’s use of all equipment for home use; • Provide a specific written statement of warranty on the equipment provided, including commercial warranties on manufactured equipment or components, and any dealer warranties on adapted or custom-fabricated items; and • Provide, or advise the beneficiary about how to access information, equipment, and supplies to maintain Universal precautions. | <p>include coverage for these beneficiary needs for information, communication and instructions on use of the equipment.</p> |
| <p><u>Condition of the Home</u></p> <p>The supplier shall:</p> <ul style="list-style-type: none"> • Assess the beneficiary’s home for safety concerns related to the use of the equipment and supplies provided; and • Evaluate the adequacy or electricity and/or water that is needed to safely operate the equipment provided. Notify the treating physician immediately if there are health-related or other problems that impose a threat to the safe operation and function of the equipment. <p>In addition to the General Product Specific Service Requirements:</p> <ul style="list-style-type: none"> • When replacing supplies through mail order delivery, the supplier shall ensure the instructions on the operation, safety, maintenance, repair, replacement, warning, and manufacturer’s instructions are packaged with the products. | <p>This would not be applicable to sales of over-the-counter items as the pharmacist would not be in the patient’s home.</p> <p>For products that are provided in the patient’s home, pharmacists would follow the prescription instructions and provide the patient with information required for use of the equipment in accord with their professional responsibilities as licensed pharmacists.</p> <p>For products that are provided in the patient’s home, pharmacists would follow the prescription instructions and provide the patient with information required for use of the equipment in accord with their professional</p> |

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| | responsibilities as licensed pharmacists. (See Appendix A scope of pharmacy practice and Appendix D on professional conduct.) |
| <i>Training/Instruction to Beneficiary and Caregiver(s)</i> | |
| <p>The supplier shall ensure that the beneficiary and/or caregiver(s) receive all necessary instructions and training related to the use and maintenance of the equipment.</p> <p>The supplier shall:</p> <ul style="list-style-type: none"> • Provide, or coordinate the provision of, appropriate instruction and information related to the set-up, features, routine use, troubleshooting, safety, cleaning and maintenance of the equipment and supplies provided. Such instruction may be in written, video, or electronic format supplemented with oral instructions; • Document in the service plan that such instructions were provided; • Inform the beneficiary and/or caregiver how to contact the supplier for routine and after-hours equipment problems; • Provide information and/or instruction about infection control issues related to use of the equipment and/or supplies; and • Ensure that the beneficiary and/or caregiver know when and how to obtain help if a medical emergency arises. <p>The supplier shall provide to the beneficiary/caregiver and/or review:</p> <ul style="list-style-type: none"> • A copy of the user instruction manual and warranty; • The beneficiary's rights and responsibilities as a consumer; • The supplier's privacy practices; • The process to communicate compliments and complaints or concerns; and • Important telephone numbers for repair, emergencies, and customer service. | <p>State pharmacy laws and regulations require pharmacists to have prescriptions and consult with the patient's physician as needed for any changes or refinements to a patient's prescription and to follow any treatment plan of the patient's physician which would include providing the patient with any needed information and pharmacist consultation on the use of the equipment and any needed supplies. Pharmacy laws and regulations as well as pharmacists' professional standards require pharmacists to provide patient consultation and information required for the use of equipment and supplies. (See, Appendix A, Pharmacists Scope of Pharmacy Practice Laws.)</p> <p>Each pharmacy has a pharmacist in charge or pharmacist manager. All pharmacies are required by the state board of pharmacy pursuant to state pharmacy laws and regulations to have a pharmacist-in-charge (PIC) or pharmacist manager that would oversee the practice of pharmacy which would include services to Medicare beneficiaries. (See Appendix C for state laws for pharmacists in charge or pharmacist managers.)</p> |

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| <p>In addition to the General Product Specific Service Requirements, the supplier shall provide instruction to the beneficiary and/or caregiver for specific equipment as follows:</p> <p><i>Lancet (Lancing Device and Platforms)</i></p> <p><u>Equipment Usage</u></p> <ol style="list-style-type: none"> 1. How to use lancet to properly obtain a blood sample. 2. How to dispose of lancet/platform safely. 3. How to clean and maintain lancet device and platform. <p><u>Safety</u></p> <ol style="list-style-type: none"> 1. How to dispose of lancets: <ul style="list-style-type: none"> • Do not discard into household trash, as a used lancet might accidentally stick someone; and • Place used lancets into a plastic container, such as an empty laundry detergent bottle or plastic water bottle. Seal the container when about ¾ full. 2. Check with local trash disposal agency about proper disposal of lancets. <p><i>Laser skin-piercing device and disposable film cartridge</i></p> <p><u>Equipment Usage</u></p> <ul style="list-style-type: none"> • How to select proper depth of penetration, set and use the device, and obtain a blood sample for the glucometer. • How to clean and maintain the device. • Need to keep battery properly charged or to replace as indicated. • How and when to replace the disposable | <p>The pharmacist’s professional responsibilities and following the prescription instruction would include coverage for these beneficiary needs for information, communication and instructions on use of the equipment.</p> <p>For all of these diabetic testing and supplies including lancets, laser skin piercing devices, and glucose monitors, calibration solutions and test strips, pharmacists in compliance with their professional responsibilities, provide the patient with any needed information and consultation on the use of the equipment and any needed supplies including any particular instructions required for proper use of the products. Pharmacy laws and regulations as well as pharmacists’ professional standards require pharmacists to provide patient consultation and information required for the use of equipment and supplies. (See, Appendix A, Pharmacists Scope of Pharmacy Practice Laws.)</p> |
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film/lens shield cartridge.

Home Blood Glucose Monitor

Equipment Usage

- Usage is likely to vary slightly for each model
- How to prepare for use, insert a lancet in the lancet device, use test strips, use lancet device to obtain a blood sample, use blood glucose monitor to the results, and record test results if the monitor does not automatically record them.

Home Blood Glucose Monitor with integrated lancing/blood sample

- These monitors have an integrated lancing device and therefore do not require a separate lancing device as with typical monitors.
- Some of these monitors also do not require test strip handling or coding.
- Need to follow manufacturer's manual for specific usage instructions.

Home Blood Glucose Monitor with integrated voice synthesizer

- These monitors use a voice prompt to aid visually impaired users through the testing process, step-by-step. See owner's manual for specific usage instructions.

All Glucometers

Cleaning/Maintenance

- How to keep glucose monitor clean
- Need to avoid getting moisture in the code key slot or in the test strip opening.

Troubleshooting

- What to do if unexpected result is obtained.
- How and when to check and replace battery.

Factors that can affect the accuracy of a test include:

- Any alcohol in the drop of blood from cleaning skin with rubbing alcohol
- Dirty hands. Wash hands thoroughly with soap and water before testing
- Wet hands. Even a small amount of water can affect blood sugar results. Dry hands thoroughly after washing them
- Scraping the skin or milking the blood drop and contaminating it with other materials such as

fluids or skin

- Using too small or too large a drop of blood
- Blood glucose monitors cannot detect very low (below 40mg/dl or 2.2mmol/L) or very high (above 400mg/dl or 22.2mmol/L blood sugar levels
- Blood sugar levels vary according to diet, activity level, and insulin or diabetes medication
- Improper coding of the monitor
- A monitor that has been dropped or damaged
- Test strips that have been stored improperly or have expired
- Multiple vials of testing strips from different calibration codes are being used at the same time
- Using test strips that are damaged or previously used
- Not using the correct brand of test strips
- Monitor has been stored at improper temperature (extreme hot or cold)
- Extremes of humidity (>90% or <10% relative humidity)
- Extremes of altitude (greater than 10,000 feet or 3000m ft above sea level)
- Significant body fluid loss or dehydration

Normal, low and high calibrator solution/chips

Equipment Usage

- How to use control solution/chips to maintain accurate readings from home blood glucose monitor
- Need to check the test strip vial label for the correct calibrator solution/chip range before running a test. If the monitor is functioning properly, results will fall within this specified range.
- How to insert test strip with calibrator solution or calibrator chip into monitor to get results.
- When to run a calibrator solution/chip test: before first use of system, weekly thereafter; if test strip vial cap left open, blood glucose monitor dropped, test results are higher or lower than expected; and to check the performance of the blood glucose monitor and test strips.

Storage

- How and where to store

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| <ul style="list-style-type: none"> • How long to store a batch of calibrator solution/chips after opening the vial <p><i>Blood Glucose test/reagent strips (for monitor)</i> <u>Cleaning/Maintenance</u> These test strips are to be used with the home blood glucose monitor. The supply shall educate beneficiary and/or caregiver on usage and storage of test strips.</p> <p><u>Usage</u></p> <ul style="list-style-type: none"> • Need to use correct test strips. Each home blood glucose monitor requires a specific type of test strip, usually brand specific (check manual) • Need to check expiration date on the bottle of testing strips. Do not use test strips after the expiration date on the bottle • Need to match code number on the testing strips bottle with the number on the meter • How to change code number on monitor, if indicate • How to handle and store test strips | |
| <p><i>Follow-up</i> General Product Specific Service Requirements The supplier shall provide beneficiary follow-up services, consistent with the service(s) already provided, the beneficiary’s diagnosis, and any recommendations from clinical referral sources. The supplier shall:</p> <ul style="list-style-type: none"> • Communicate with the treating physician or clinical team regarding outcomes of monitoring, maintenance, and operation of all equipment provided to the beneficiary; • Periodically review the service plan with treating physician or clinicians regarding the beneficiary’s medical condition and the continued use and tolerance of the equipment and supplies; and <p>Communicate any clinically significant beneficiary concerns, needs, and condition changes that affect the beneficiary’s use of equipment and supplies to the treating physician within 24 hours of determination.</p> | <p>For all of these products, pharmacists in compliance with their professional responsibilities, pharmacists provide the patient with any needed information and consultation on the use of the equipment and any needed supplies including any particular instructions required for proper use of the products. Pharmacy laws and regulations as well as pharmacists’ professional standards require pharmacists to provide patient consultation and information required for the use of equipment and supplies. (See, Appendix A, Pharmacists Scope of Pharmacy Practice Laws.)</p> |