THE FOLLOWING CHECKLIST IS PROVIDED FOR DISCUSSION PURPOSES ONLY RELATED TO THE NATIONAL COMMUNITY PHARMACY ASSOCIATION OWNERSHIP WORKSHOP AND DO NOT CONSTITUTE LEGAL ADVICE FROM BROWN & FORTUNATO LAW FIRM. INDIVIDUALS OR ENTITIES BUYING OR SELLING A PHARMACY ARE ADVISED TO SEEK COUNSEL BEFORE PROCEEDING. THIS CHECKLIST SHALL NOT BE USED BY ANYONE FOR PURPOSES OUTSIDE THE SCOPE OF THE OWNERSHIP WORKSHOP.

REGULATORY AND COMPLIANCE DUE DILIGENCE CHECKLIST

Company Name: ______________________________________________   Date: ___________
Address: ____________________________________________________
Telephone and Fax Numbers: ____________________________________
Person Completing Checklist: _________________________________

Supplier Number Issues

1. What is the company’s Medicare DMEPOS supplier number(s)?__________________
   Please attach copies of most recent supplier re-enrollment applications.

2. How many physical locations does the company have? ______
   Give the addresses of all locations and their corresponding supplier numbers:

3. Has the company closed any locations in the past 5 years?   ____ Yes      ____ No.
   If “Yes,” give the address of all locations closed in the last 5 years and reasons for
   closure.

   If “Yes,” give address and attach copy of pharmacy and pharmacist-in-charge licenses.

5. Does any location that dispenses prescription drugs seek Medicare/Medicaid
   reimbursement for the drugs? _____ Yes     _____ No. If “Yes,” give the address of all
   of the locations.

Medicaid Issues

6. Is the company a qualified provider to the state Medicaid program? _____ Yes ____ No.
   If “Yes,” give the provider number: ____________________________________________
   Obtain copy of application.
Employment and Independent Contractor Issues

7. Does the company utilize independent contractors? _____ Yes      _____ No.
   If “Yes,” list the names of the independent contractors, how paid and the type of work
   they perform, and attach a copy of any contracts.

8. Does the company have any part-time employees? _____ Yes      _____ No.
   If “Yes,” list the names of the employees, how paid, and the type of work they perform.
   Attach a copy of any contracts.

9. Does the company utilize marketing representatives? _____ Yes      _____ No.
   If “Yes,” list the names of the marketing reps, describe their duties and compensation,
   and attach copies of any contracts.

10. Does the company have any medical directors? _____ Yes      _____ No.
    If “Yes,” list the names of the physicians, describe their duties and compensation, and
    attach copies of any contracts.

11. Does the company have any employment or personal service contracts with any
    healthcare providers? _____ Yes      _____ No.  If “Yes,” list the names of the providers,
    describe their duties and compensation, and attach copies of any contracts.

12. Does the company have any loan closet arrangements? ____ Yes   ____ No.  If yes,
    describe arrangement and attach copies of any contracts.

Referral Source Issues

13. Does the company have any written or verbal relationship with any healthcare referral
    sources, such as physicians, hospitals, home health agencies, respiratory therapists, etc.?
    _____ Yes _____ No.  If “Yes,” list the names of the referral sources, describe any
    compensation, and attach copies of any contracts.

Documentation Issues

14. Does the company have appropriate Certificates of Medical Necessity (“CMNs”) in the
    patients’ files?   _____ Yes   _____ No.  If “No,” give an explanation.

15. Describe how the company obtains CMNs.

16. Is Section C of the CMN always properly completed with a narrative description of the
    prescribed DME? _____ Yes _____ No.  If “No,” give an explanation.
17. State who routinely completes Section B of the CMNs.

18. Does the company have appropriate written prescriptions or orders prior to delivery in the patients’ files? _____ Yes _____ No. If “No,” give an explanation.

19. Does the company have properly signed Assignments of Benefits in the patients’ files? _____ Yes _____ No. If “No,” give an explanation.

20. Does the company have evidence that Medicare beneficiaries received a copy of the current 30 supplier standards? _____ Yes _____ No. If “No,” give an explanation.

21. Does the company have the appropriate delivery receipts signed by the patients in the files? _____ Yes _____ No. If “No,” give an explanation.

22. Does the company have the appropriate test results or other documentation supporting provision of the equipment in the patients’ files? _____ Yes _____ No. If “No,” give an explanation.

23. Describe any other documentation issues noted.

24. What audit procedures have been performed to verify receipt of information in questions 13-24? When was the last audit completed? Please attach a copy of audit tool and results.

25. Have any licenses, permits, registrations or certificates of authority to operate any part of the company ever been revoked, suspended, investigated or voluntarily surrendered after receiving notice of such investigation by any federal, state or local governmental entity or private accrediting agency? _____Yes _____No If “Yes,” give an explanation.

26. Is the company aware of any potential or ongoing litigation, audit, overpayment request/demand, review or dispute with any payor, healthcare provider, governmental agency or private accrediting agency, which, if successful, would result probation or suspension or a status of less than full licensure, certification or accreditation, result in the company’s payment of $1,000.00 or more or otherwise have an adverse effect on the company? _____Yes _____No If “Yes,” give an explanation.

27. Has the company ever been involved in any litigation, audit, overpayment request/demand, review or dispute with any payor, healthcare provider, governmental agency or private accrediting agency which resulted in the company’s payment of $1,000.00 or greater? If yes, give an explanation.
28. Has the company, or have any of its locations, ever received an unannounced visit by employees or agents of the carrier, such as benefits integrity investigators, medical reviewers, NSC employees, etc.? If so, please attach copies of any letters given to the company at the time of the visit, and provide information on results of visit.

29. Is the company operating with all necessary licenses, permits, registrations, and certificates of authority? _____Yes _____No If “No,” give an explanation. Obtain copies of all operative licenses, permits, registrations, certificates, etc.

30. Have any current licenses, permits, registrations or certificates of authority been issued on a temporary or less that full-status basis? _____Yes _____No If “Yes,” give an explanation.

31. Please indicate below all licenses, permits, registrations and certificates of authority which have been issued and are currently in effect for the company. (Check all applicable boxes)

<table>
<thead>
<tr>
<th>Description</th>
<th>License/Permit No. and Date of Issuance</th>
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<tbody>
<tr>
<td>☐ Pharmacy license</td>
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<tr>
<td>☐ Pharmacist-in-charge license</td>
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<td>☐ DEA license</td>
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<tr>
<td>☐ Business license</td>
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<td>☐ Occupational and sales tax license</td>
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<td>☐ Oxygen distributor’s license</td>
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<td>☐ DME license</td>
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<td>☐ Oxygen transfilling registration</td>
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<td>☐ Other (describe):</td>
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32. Has any shareholder, owner, officer, director, manager or employee of the company ever been convicted of a felony, or been excluded from any private health care benefit program or any state or federal health care benefit program including the Medicare or Medicaid programs? _____Yes _____No. If “Yes,” give an explanation.

33. List all shareholders, owners, officers, directors, and all employees. Include the person’s full legal name, home address, date of birth, social security number and job title. Please note if any of the shareholders are physicians or other licensed health care providers.
Corporate Compliance Issues

34. Is the company compliant with the 30 supplier standards?

35. Does the company have a corporate compliance plan/program? Please provide a copy.

36. Who is the corporate compliance officer?

37. Are employees, prescribing physicians, independent contractors and referral sources checked against the OIG exclusions database? How often? Is this verification documented? Please attach samples of documentation maintained.

38. What, if any, training occurs and how is it documented? Please attach samples of training materials.

39. What kinds of audits have been performed under the corporate compliance program? Please attach sample copies of audits.

40. Does the company have a hotline? Please attach copies of hotline logs and logs indicating resolution of hotline calls.

Environmental and OSHA Issues

41. Does the company utilize potentially hazardous materials? If so, are MDS sheets readily available? Please attach copies of relevant policies and procedures.

42. Does the company work with potentially biohazardous materials, including biohazardous or medical waste or body fluids? Please attach copies of policies and procedures.

43. Does the company comply with blood-borne pathogens requirements? Please attach copies of relevant safety precautions policies and procedures, including needlestick injuries.

44. Does the company comply with OSHA requirements re: workplace injuries - such as those to prevent back strain etc. (See proposed OSHA requirements for nurses and home health aides).

Employment Issues

45. Does the company have formalized and documented employee files?
46. Does the company verify the immigration status of new hires?

47. Does the company have a disciplinary policy? Is it consistently enforced?

48. Does the company have any issues re: compliance with the Americans with Disabilities Act?

49. Does the company have any issues re: compliance with the age discrimination laws?

50. Does the company have any issues re: compliance with other non-discrimination laws?

**FDA and Pharmacy Issues**

51. Does the company perform any compounding of drugs, or any relabelling or repacking? If so, please provide copies of compounding logs, histories of receipt of prescriptions for compounded products, marketing materials, etc.

52. Does the company perform any oxygen transfilling?

53. If so, does the company comply with CGMPs and labeling requirements?

54. Can the company respond appropriately to a recall or other request from governmental agencies? Please attach copies of relevant policies and/or procedures.

**HIPAA**

55. Does the company provide privacy notices to patients?

56. Does the company have privacy policies? Please attach copies of such.

57. What measures has the company taken to assure the privacy of patient records?

58. Where is the company in the process of complying with the electronic transactions and code sets standards?

59. What are the company’s data security policies and procedures? Attach a copy.

60. Attach a copy of the company’s records disclosure accounting form/log.

61. Has the company ever performed any audits on patient data privacy or security?
Other Issues

63. Does the company provide information to patients in a culturally and linguistically appropriate manner? (See DHHS’s Office of Civil Rights guidances). Describe what these are.