AmerisourceBergen
Besse Medical

Completion Procedure for 590-Controlled Substance Questionnaire

Dear Valued Customer:

Please complete the attached 590-Controlled Substance questionnaire in full and return to Accountsetup@besse.com. A completed and approved questionnaire is necessary to be able to place controlled substance orders.

Please include a copy of the following documents with your completed questionnaire:

- State Medical License
- State issued controlled substance registration (if applicable)
- DEA license
- Photos (if applicable)

Again, please complete the questionnaire in full and scan/email to Accountsetup@besse.com.

Thank you in advance for your cooperation.

Besse Medical

This questionnaire is to be completed by the distributor owner/authorized representative and ABC associate during an on-site visit.

Form will not be processed until ALL questions are answered in full.

Name of ABDC associate: ____

Phone of ABDC associate: ____

Servicing distribution center(s) _____________________________________

SECTION I – General Information

1. Distributor name (as it appears on the DEA registration): ____

DBA: ____

Has the distributor ever operated under another name? Yes ☐ or No ☐ If yes, please list: ______________________________

Will Besse be this customer's primary wholesaler? Yes ☐ or No ☐ If no, list primary: ___________________________________

If no, what percentage of distributor's business will be serviced from Besse?____

2. Distributor address (as it appears on the DEA registration):

Street____ City____

State_________________________ Zip_________________ Phone: ____

Email:____ Website:_______________________________________

3. Select the following reason for CSRA review:

☐ Start-up business.

☐ Established business **changing** supplier(s) to Besse. List current supplier(s):__________________________________

☐ Established business **adding** Besse as supplier(s). List current supplier(s): ____________________________________

☐ Change in practitioner – indicate existing account #: ____

☐ Change in ownership – indicate existing account # ____

☐ Updated CSRA 590 form – indicate existing account #: ____

Reason for updated form:

____

____

☐ Change from Secondary to Primary status – indicate existing account #:____

☐ Change from RX only purchasing to eligible for control purchasing – indicate existing account #:___________________

4. Does this distributor export? Yes ☐ or No ☐ If yes, does the distributor export controlled substances? Yes ☐ or No ☐

5. What percentage of the following describes the distributor's customer segments? Selection(s) should add up to 100%.

Retail ______% Long term care _______% Compounding _______% Internet _______%

Mail order _______% Hospice _______% Specialty_______% Gov't/DOD_______%

6. Select if you have a current account with any other ABC subsidiary and indicate applicable account #.

☐ Oncology - account #______________________________ ☐ ASD – account # ________________________________

☐ MWI – account #________________________________ ☐ ABDC – account # _____________________________________

☐ ICS – account # ______________________________ ☐ SmartSource – account # ___________________________________

SECTION II - Licenses

7. Distributor state license #: ________________________________DEA license #: _____________________________________

   DEA Business Activity Code____

8. Controlled substance state license (if applicable): ____

9. Other licenses (exporter, re-packager, etc.): ____

10. Please list applicable license #'s (state and federal) for ALL states you deliver controlled substance and/or Gabapentin drug products to. Attach additional sheet as addendum if necessary.
____

SECTION III – Distributor Personnel & Ownership

11. Ownership type (*check all that apply*): Proprietor ☐ Corporation ☐ Partnership ☐

12. Are any of the owners a licensed pharmacist or prescribing physician? Yes ☐ or No ☐ If yes, please list license number(s) and state(s): ____

13. Are any of the owners associated with or own another distributor? Yes ☐ or No ☐
    If yes, please provide additional details in the comments and observations section.

14. Please provide ownership information below (*if applicable*):

Owner name	State of residence	Number of years owner has operated as a distributor.	% of ownership

15. Name of manager-in-charge ___________________________________License # (if applicable):__________________________

16. Name/title of person responsible for regulatory compliance _________________________License # (if applicable)______________

SECTION IV – Sanctions/Discipline

17. Has the distributor had a DEA registration or state license/registration (including any state where the distributor does business) suspended, revoked or disciplined within the last 10 years? Yes ☐ or No ☐ If yes, give details (when, why, etc.)

____
____

18. Is this distributor currently part of an active investigation at the federal, state or local level? Yes ☐ or No ☐
If yes, please provide details (when, why, etc.)

____
____

19. Has a supplier ever suspended or ceased controlled substance sales to the distributor?
Yes ☐ or No ☐ If yes, give details (when, why, etc.)

____
____

20. Has the owner, family member, or any employee of the distributor had a DEA registration or state license/registration suspended, revoked or disciplined within the last 10 years? Yes ☐ or No ☐ If yes, give details (when, why, etc.)

____
____

21. Has the manager, person responsible for regulatory compliance, owner, or employee of the distributor had any administrative, civil, and/or criminal action imposed by any regulatory/law enforcement entity (state, local, federal) within the last 10 years?
Yes or No If yes, give details (when, why, etc.)

____
____

SECTION V – Controlled Substance Distribution

22. Are other businesses or business activities located at the same location that purchase controlled substance and/or Gabapentin products (retail pharmacy, manufacturer, etc.)? Yes ☐ or No ☐
If yes, identify and explain

____
____

23. Check the following types of products (**based on dosage units**) you expect to purchase from Besse.
Selection(s) should add up to 100%.

Non-controlled Rx_______% of total purchases   Controlled substances___________% of total purchases

HBA/OTC_______% of total purchases   Listed chemicals_____________% of total purchases

24. What is your ratio of in-state customers vs out-of-state customers?

In-State customer ratio ____________%   Out-of-State customer ratio_____________%

SECTION V – Controlled Substance Distribution con't

25. Please provide the anticipated or actual usage of the top 10 controlled substance or listed chemical product purchases. Start-up entities please provide estimates:

Controlled substance product	Strength	Dosage Form	Monthly usage values in dosage units

SECTION VI – Due Diligence

26. Are orders reviewed to determine if the order is suspicious? Yes ☐ or No ☐

27. Does the distributor have a due diligence program to vet prospective customers and customers that purchase significant quantities of controlled substances? Yes ☐ or No ☐

28. Which of the following are included in your due diligence processes? (*Check all that apply*):

☐ Customer questionnaire ☐ On-site visit ☐ Review of dispensing/usage Information ☐ Public records/internet search

☐ Verification of applicable registrations and licenses ☐ Other (Please list): ____

SECTION VII – Comments & Photos

29. Attach and date photographs of distributor building (2 of inside, 1 of **entire exterior front** and 1 of the back of the facility).

Other comments/observations:

SECTION VIII – ACKNOWLEDGMENT

By signing below, distributor acknowledges that:

Besse relies on the information provided on this form to help determine whether it will distribute controlled substances to Distributor. Distributor agrees to inform Besse of any changes to its business that would impact the accuracy or completeness of the information contained herein.

Besse reserves the right, within its sole discretion, to refuse to ship controlled substances to any customer. Any materially incorrect information on the CSRA Form 590 will be grounds for Besse, at its sole discretion, to immediately cease distribution of any or all controlled substances to Distributor and/or to terminate Besse's relationship with Distributor. Distributor has an effective compliance program and adheres to all requirements imposed upon it for the distribution of controlled substances as promulgated in the CFR and by any applicable federal, state or local board of Distributor or other regulatory body.

Distributor will indemnify and hold harmless Besse, its parent companies, affiliates, subsidiaries, shareholders, officers, directors, employees, agents and representatives from any and all economic damage that results from Distributor providing BESSE with materially incorrect information on this form or from failing to have in place an effective compliance program.

DISTRIBUTOR OWNER/AUTHORIZED REPRESENTATIVE:

______________________________	______________________________
Name (Print)	Signature
______________________________	______________________________
Title	Date

I, as an authorized Besse representative, have discussed with Owner/Distributor BESSE's commitment to preventing the diversion of prescription drugs and the importance of providing complete and accurate responses on this form.

BESSE ASSOCIATE:

______________________________	______________________________
Name (Print)	Signature
______________________________	______________________________
Title	Date

*****IMPORTANT NOTE:** Both Besse associate and distributor owner/authorized representative signatures MUST be present to initiate CSRA review.