

Medicare Compliance Addendum

To the extent a Supplier or Independent Contractor is deemed a first tier, downstream or related entity in accordance with 42 C.F.R. Parts 422 and 423, Supplier or Independent Contractor (the “FDR”) hereby agrees to this Medicare Compliance Addendum (the “Compliance Addendum”). In the event of any conflict or inconsistency between the terms of the Compliance Addendum and the terms of the Agreement or any applicable Medicare Advantage Addendum, the terms of the Compliance Addendum shall apply. Any term not defined herein shall have the meaning set forth in the Agreement.

Customer (the “Plan”) has contracts to administer Medicare Advantage Plans and/or Medicare Part D plans (collectively “Medicare”) for the Centers for Medicare & Medicaid Services (“CMS”) of the U.S. Department of Health and Human Services (“HHS”) to administer Medicare benefits within certain counties. FDR’s performance of the Services under the Agreement shall include the provision of healthcare and or administrative services related to the Plan’s Medicare business. Payment received for FDR’s services, are in whole or in part, from Federal funds.

The Plan is a licensee of the BlueCross Blue Shield Association. As a licensee, we participate in Medicare Advantage Network Sharing. The Plan must ensure that its network sharing providers agree to furnish services to other Licensee Members as well as extend the same contractual terms, including but not limited to negotiated pricing and hold harmless protections, to all Blue Cross and/or Blue Shield Medicare Advantage PPO members and/or Medicare Advantage HMO members for Transplant Facility services, as applicable. The Plan must ensure that its Medicare Advantage PPO and/or HMO Transplant provider network(s) meets CMS standards for accessibility as set forth in 42 C.F.R. §422.112 and CMS’s *Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance*, and that its provider and supplier contracts and incorporated procedures include all required Medicare Advantage provisions. The Plan agrees to produce, upon the request by CMS or its designees, governing bodies and participating network plans any books, contracts, records related to the Medicare Advantage program with regard to any Medicare Advantage services furnished or arranged for under the delegated arrangement. This is in accordance with Blue Cross and Blue Shield’s Delegation Oversight Program, as well as CMS and Federal requirements. FDRs are required to support our delegated arrangement.

FDR agrees as follows:

1. **Compliance with Medicare laws, regulations and CMS guidance:** FDR agrees to comply with all applicable Medicare laws, regulations and CMS instructions.
Regulations: 42 C.F.R §§ 422.504(i)(4)(v), 423.505(i)(4)(iv)
2. **Medicare standards of conduct and policies and procedures:** FDR agrees to make available Standards of Conduct and policies and procedures to all of its employees who provide administrative services or health care services for Regence’s Medicare business pursuant to this Agreement at the time of hire and annually thereafter. FDR may either provide:
 - a) Regence’s *Standards of Conduct* and policies and procedures to FDR’s employees,
 - or

b) FDR's own comparable Standards of Conduct and policies and procedures to FDR's employees.

Regulations: Medicare Managed Care Manual (MMC Manual), Chapter 21, §§ 50.1.3 and 50.3.1; and Medicare Prescription Drug Benefit Manual (PDB Manual), Chapter 9, §§ 50.1.3 and 50.3.1

3. **Conflict of interest:** FDR agrees to comply with Regence's *Conflict of Interest Policy* or its own conflict of interest policy that complies with CMS requirements. FDR will require its governing body, officers and senior leadership (as applicable) to sign a conflict of interest at the time of hire and annually thereafter certifying that they are free from any conflict of interest related to Medicare. *Regulations:* 42 C.F.R. §§ 422.503(b)(4)(vi)(A) and (C) and 423.504(b)(4)(vi)(A), (C) and (F)
4. **Fraud, waste and abuse (FWA) and general compliance training:** FDR agrees that all of its employees who provide administrative services or health care services for Regence's Medicare business pursuant to the Agreement participate in FWA and general compliance training within 90 days of hire and annually thereafter. *Regulations:* MMC Manual, Chapter 21, § 50.3.2; PDB Manual, Chapter 9, § 50.3.2; 42 C.F.R. §§ 422.503(b)(4)(vi)(A) and (C), 423.504(b)(4)(vi)(A), (C) and (F)
5. **Reporting compliance and FWA concerns:** FDR agrees to report compliance or FWA concerns to CMS or Regence. Reporting should occur within five days of discovery; if there is an immediate impact to beneficiary access to care and/or a financial strain, please report immediately but at least within 24 hours. Regence has a no-tolerance policy for retaliation or retribution against any employee or FDR for good-faith reporting of FWA. *Regulations:* 42 C.F.R. §§ 422.503(b)(4)(vi)(D), 423.504(b)(4)(vi)(D)
6. **Enforcement of disciplinary standards:** FDR agrees to establish and publish its own disciplinary standards, which include its expectation that employees report compliance issues and unethical or illegal behavior. FDR's disciplinary standards must state that any violation of these standards will result in appropriate disciplinary action, up to and including termination of employment. FDR's violation of this provision may result in Regence's termination of the Agreement. *Regulations:* 42 C.F.R. §§ 422.503(b)(4)(vi)(E), 423.504(b)(4)(vi)(E)
7. **Exclusion from participation in federal programs:** Pursuant to federal law, FDR certifies that neither it nor any of its employees or governing body members are on the:
 - a) List of Excluded Individuals and Entities (LEIE) from the HHS OIG; or
 - b) GSA Debarment List.If an employee or governing body member is on either list, FDR will immediately remove that person from any work related directly or indirectly to any federal healthcare program. FDR agrees to check both lists prior to hire and on a monthly basis to ensure that none of its employees have become excluded from participation in federal programs. The term "employees" includes temporary employees, volunteers and consultants. If applicable, FDR will establish a process to identify and prevent payment for claims at point-of-sale for any drugs or services prescribed, dispensed or delivered by excluded

providers. *Regulations*: 42 C.F.R. §§ 422.503(b)(4)(vi)(F), 422.752(a)(8), 423.504(b)(4)(vi)(F), 423.752(a)(6); 42 C.F.R. § 1001.1901

Exclusion from participation in government programs: FDR shall not employ or contract with any individual or entity who is excluded from participating in Medicare under Sections 1128 or 1128A of the Social Security Act (or with an entity that employs or contracts with such an individual or entity) for the provision of any Medicare services under this Agreement, including but not limited to, (i) healthcare services; (ii) utilization review; (iii) medical social work; or (iv) administrative services; and must notify Regence immediately if any such excluded individual or entity provides or performs a delegated function on behalf of Regence and other Plans participating in the delegated arrangement. *Regulations*: 42 C.F.R. §§ 422.224, 422.752(a)(8)

8. **Record retention:** FDR agrees to maintain, or assure the maintenance of timely and accurate medical, financial and administrative records, books and contracts related to services provided or arranged for by Regence as part of any delegated function, as well as the Regence's contract with CMS. Unless a longer time period is required by applicable statutes or regulations, FDR agrees to maintain such records and any related contracts for ten (10) years from the final date of our contract with CMS, the delegated arrangement period, or from the date of the completion of any audit, whichever is later, or otherwise as required by CMS. FDR agrees to comply with any document requests by Regence pursuant to an audit or to monitor FDR's compliance with the terms of this Agreement, the Compliance Addendum or these *Medicare Advantage Compliance Requirements*. FDR will provide these documents to Regence without charge. *Regulations*: 42 C.F.R. §§ 422.504(d), 422.504(e), 422.504(i)(4)(iii), 423.504(d)(2), 423.505(i)(4)(iii)
9. **Audit rights and access to records:** FDR agrees to allow the HHS, CMS, the Comptroller General or their designees, regulatory bodies, Regence, and Plans participating in the delegated arrangement, to review, audit, evaluate, collect and inspect and make copies of any books, contracts, computer or other electronic systems, including medical records and patient care documentation, and other records maintained by the FDR pertaining to services related to Regence's contract with CMS and services rendered to the members under the delegated arrangement. This right to audit, evaluate, collect, make copies of and inspect any pertinent information for any particular contract period will exist through 10 years, from the final date of the contract period, the delegated arrangement period, or from the date of completion of any audit, whichever is later, or otherwise as required by CMS. *Regulations*: 42 C.F.R §§ 422.504(d), 422.504(e), 422.504(i)(2)(i), 422.504(i)(2)(ii) and 422.504(i)(2)(iv), 422.504(i)(4)(iii), and 423.505(d)(2), 423.505(i)(2), 423.505(i)(2)(ii), 423.505(i)(2)(iv), 423.505(i)(4)(iii)

FDR's failure to comply with this section could result in referral to law enforcement and/or implementation of corrective action. *Regulations*: 42 C.F.R. Subpart O

Additionally, HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any such records directly from FDR. For records subject to review, except in exceptional circumstances, CMS will provide notification to Regence that a direct request for information has been initiated. *Regulations*: 42 C.F.R §§ 422.504(i)(2), 423.505(i)(2)

10. **Hold harmless:** In no event, including, but not limited to, nonpayment by Regence or the insolvency of Regence, shall FDR bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, or have any recourse against Regence members or persons acting on their behalf, other than Regence for covered services. This provision shall not prohibit collection of any applicable coinsurance, copayments or deductibles billed in accordance with the terms of Regence's applicable evidence(s) of coverage. Providers are expected to ensure that pre-authorizations are obtained, if needed, and/or referrals are made to contracted providers. If pre-authorization is not obtained as required, the provider may be held liable for costs. *Regulations:* 42 C.F.R §§ 422.504(g), 422.504(i)(3)(i), 423.505(g)
11. **Provider credentialing:** To the extent applicable, our credentialing process for medical professionals affiliated with, or any credentialing functions delegated to an FDR shall meet all applicable Medicare Advantage credentialing requirements and shall be reviewed and approved by Regence. Regence shall have an ongoing right to monitor and audit any credentialing program performed on its behalf. *Regulations:* 42 C.F.R. §§ 422.504(i)(4)(iv) and (5)
12. **Monitoring, delegation, and revocation:** FDR shall comply with all applicable policies and procedures of the Regence Medicare Advantage plan. Regence will oversee and monitor FDR's performance on an ongoing basis. We retain the right to approve, suspend, revoke or terminate the delegated arrangement or any such Agreement with FDR if CMS or Regence determines that FDR has (a) not performed satisfactorily under the terms of the Agreements, the Compliance Addendum or these *Medicare Advantage Compliance Requirements*, (b) failed to maintain compliance, or (c) engaged in FWA or (d) if any of our reporting and disclosure obligations is not fully met in a timely manner. *Regulations:* 42 C.F.R §§ 422.504(i)(4)(ii), 422.504(i)(4)(iii), 422.504(i)(5), 423.505(i)(4)(ii), 423.505(i)(4)(iii)
13. **Flow-down provision:** FDR shall incorporate the terms of the Compliance Addendum and these *Medicare Advantage Compliance Requirements* into any and all subcontracts entered into delegating any of FDR's obligations to Regence under the Agreement or Compliance Addendum. *Regulations:* 42 C.F.R §§ 422.504 (i)(3), 422.504 (i)(4)(v), 423.505 (i)(3)(iii), 423.505(i)(4)
14. **Member records:** All information about a member shall be treated as confidential so as to comply with all applicable federal, state, and local laws, rules, regulations and Medicare confidentiality and enrollee record accuracy requirements including:
 - a) Abiding by all federal and state laws regarding confidentiality and disclosure of medical records, or other health and enrollment information
 - b) Ensuring that medical information is released only in accordance with applicable Federal or State law, or pursuant to court orders or subpoenas
 - c) Maintaining the records and information in an accurate and timely manner
 - d) Ensuring timely access by enrollees to the records and information that pertain to them. In addition, the FDR agrees to abide by our Business Associate Agreement, CMS and Federal requirements and the confidentiality requirements of the Medicare Advantage Program as set forth in 42 C.F.R. §§ 422.118.

Regulations: 42 C.F.R §§ 422.504(a)(13), 422.118, 423.505(b)(14)

15. **Dual eligible members:** If FDR is a health care provider, FDR agrees that, for all members eligible for both Medicare and Medicaid, members will not be held liable for Medicare Part A and B cost sharing when the state is responsible for paying such amounts. Regence will inform FDR of Medicare and Medicaid benefits and rules for members eligible for Medicare and Medicaid. FDR may not impose cost-sharing that exceeds the amount of cost-sharing that would be permitted with respect to the individual under Title XIX if the individual were not enrolled in such a plan. Providers will: (1) accept Regence's payment as payment in full, or (2) bill the appropriate state source. *Regulations:* 42 C.F.R §§ 422.504(g)(1)(iii), 422.504(i)(3)(i)
16. **Regence's contractual obligations:** FDR's services and activities pursuant to the Agreement are consistent and comply with Regence's contractual obligations. *Regulations:* 42 C.F.R. §§ 422.504(i)(3)(iii), 423.505(i)(3)(iii)
17. **Prompt payment:** If FDR is a health care provider, Regence's contract or written agreement with FDR shall establish payment terms and include a prompt payment provision. *Regulations:* 42 C.F.R. §§ 422.520, 422.520(b)(1), 422.520(b)(2), 422.504(c), 423.505(i)(3)(v), 423.520
18. **Downstream entity and provider approval:** If Regence delegates to another organization the selection of providers, contractors or subcontractors, Regence retains the right to approve, suspend or terminate any such arrangement to furnish services to Regence members. Notwithstanding, this right shall be exercisable only with respect to such Regence members and not members of other Blue Cross or Blue Shield Plans. Regence further agrees to exercise this right consistently with CMS laws and policies regarding provider participation and when a provider's participation poses a risk to the health or safety of Regence members. *Regulations:* 42 C.F.R §§ 422.504(i)(5)
19. **Amendments required by law:** If Medicare laws, regulations or CMS guidance require a change to any provision of the Compliance Addendum or these *Medicare Advantage Compliance Requirements*, the Compliance Addendum will be deemed amended to conform with the law, regulation, or guidance on the date said requirements become effective. Regence will make reasonable business efforts to notify FDR of those changes, but in no event does any lack of notice change the applicability of federal law.
20. **Location of services:** FDR agrees that it shall not perform functions offshore nor delegate functions to offshore entities or persons, without obtaining advanced approval in writing from Regence and demonstrating compliance with CMS guidelines and Regence policies, terms and conditions. Additionally, no Regence information, member information or Protected Health Information shall leave the United States or be accessible or viewable outside of the United States without strict information security and privacy agreements, oversight and practices in place.
21. **Non-discrimination:** FDR agrees to provide covered services to members without regard to race, ethnicity, national origin, religion, gender, age, mental or physical disability,

sexual orientation, genetic information or source of payments. *Regulations:* MMC Manual, Chapter 4, § 10.5.

22. **Non-covered services:** An FDR that is a health care provider shall not bill members for items or services that are not covered services unless, prior to furnishing the item or service, FDR requests pre-authorization from Regence and FDR and the member receive a written denial. FDR acknowledges that CMS guidance states that Advance Beneficiary Notices (ABNs) cannot be used for Medicare Advantage members. In order to bill such members for non-covered services, FDR must obtain an organization determination as addressed in 42 CFR 422.566.
23. **Preclusion list:** FDR shall ensure that providers will not be eligible for payment from Regence and Plans participating in the delegated arrangement and will be prohibited from pursuing payment from members if the provider is included on the CMS preclusion list (as defined in 42 C.F.R. § 422.2) after the expiration of the 60-day period specified in 42 C.F.R. § 422.222. The provider will be held financially liable for services, items, and drugs that are furnished, ordered or prescribed after the expiration of such 60-day expiration period. *Regulations:* 42 C.F.R. §§ 422.222, 422.224, 422.504(i)(2)(v)
24. **Enrollment advice:** If FDR is a health care provider, FDR shall remain neutral to the extent FDR assists any beneficiary with Medicare enrollment decisions. Please see more information about provider responsibilities for this in the *Medicare Advantage Plans* section of this manual. *Regulations:* MMC Manual, Chapter 3, § 60.3
25. **Responsibility and oversight:** Regence maintains ultimate responsibility for adhering to and otherwise complying with all terms and conditions of its contract with CMS and may only delegate activities or functions in a manner consistent with Regence's contractual obligations to CMS. *Regulations:* 42 C.F.R. §§ 422.504(i)(1), 422.504(i)(3)(ii), and 422.504(i)(3)(iii)
26. **FDR contracting requirements:** If Regence performs delegated functions as described above, all required Medicare Advantage provisions, including but not limited to those identified at 42 C.F.R. §422.504 and the Medicare Managed Care Manual (MMCM), Chapter 11, Section 100, as amended from time-to-time, apply to FDR contracts. Such contractual requirements are linked for reference: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c11.pdf>
27. **Data and reporting requirements:** FDR agrees to cooperate with Regence by providing all information necessary for Regence to meet its Medicare Advantage reporting obligations, including but not limited to, providing data necessary to characterize the context and purpose of each service furnished to Regence members . *Regulations:* 42 C.F.R. §§ 422.310, 422.516, 422.2460
28. **No-cause termination:** If FDR is a health care provider, Plan's contract with FDR contains a no-cause termination clause, such clause shall provide for at least sixty (60) days' written notice. FDR must refer to its Participating Provider Agreement for specific termination notice requirements, which shall be in accordance with regulatory requirements. *Regulations:* 42 C.F.R §§ 422.202(d)(4)

29. **Enrollee protection and continuation of benefits:** In the event of Regence's insolvency or other cessation of operations, Regence's services to its members, including those delegated to FDR, will continue through the period for which the CMS payment has been paid to Regence, and services to Regence members confined in an inpatient hospital on the date of insolvency or other cessation of operations will continue until their discharge. *Regulations:* 42 C.F.R. §§ 422.504(i)(3)(i), 422.504(g), 422.318(c), 423.505(g).

FDR agrees, that (i) the hold harmless and continuation of benefits provisions above shall survive the termination of the delegated arrangement regardless of the cause giving rise to the termination and shall be construed to be for the benefit of Regence members, and that (ii) these provisions supersede any oral or written contrary agreement now existing or hereafter entered into between Regence and their members or persons acting on their behalf that relates to liability for payment for, or continuation of, covered services provided under the terms and conditions of these clauses.

30. **508 compliance:** If FDR supplies a member-facing internet website on behalf of Regence, the website must be compliant with Section 508 of the Rehabilitation Act for web-based technology and information standards for people with disabilities: <http://section508.gov>

Definitions and Agreement terms:

Any term not defined in this document shall have the meaning set forth in the Agreement. The terms of this Medicare Advantage compliance requirements shall become a part of the Medicare Advantage Supplier/Independent Contractor Compliance Addendum and shall be specifically incorporated into the terms of the Agreement. In the event of any conflict or inconsistency between the terms of the Compliance Addendum and the terms of the Agreement or any Medicare Advantage Addendum(s), the terms of the most current Compliance Addendum shall apply.