The Complete Guide:

4-Steps to Executing an Effective Risk Assessment Strategy

Plus 4 sample risk assessment question set templates

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A proactive approach to regulatory compliance

Healthcare compliance is serious business with consequences beyond endangering safety and quality. Penalties for regulatory noncompliance are steep in terms of monetary fines, exclusion from participation in federal healthcare programs, prison time, and reputational damage. Consider that:

- In 2020, the U.S. Department of Health & Human Services' Office of Inspector General (OIG) reported 624 criminal actions against individuals or entities that engaged in crimes impacting HHS programs and 791 civil actions (e.g., false claims lawsuits and civil monetary penalty settlements).
- The OIG excluded 2,148 individuals and entities from participating in federal healthcare programs including Medicare and Medicaid.
- A West Virginia hospital recently paid $50M for violating the Stark Law and Anti-Kickback Statute by knowingly paying improper compensation to physicians based on the physicians' referrals.
- A Louisiana physician was sentenced to 18 months in prison and ordered to pay $366,000 in restitution for receiving illegal kickback payments from a drug testing lab.

What's your healthcare organization's risk level for violating federal, state, or accrediting body regulations? And on the finance side, is your organization taking the right steps to shore up revenue by avoiding denied claims that result in decreased reimbursement?

Risk probability shouldn't be a guessing game: All providers and organizations that participate in federal healthcare programs must regularly conduct risk assessment to identify weaknesses in operations that may lead to compliance violations and lost revenue. Areas ripe for analysis include:

- Billing
- Credentialing
- Provider financial arrangements and transactions (including gifts and other non-monetary compensation)
- Privacy and security issues covered by the Health Insurance Portability and Accountability Act (HIPAA)

Why conduct risk assessment?

Risk assessment is a proactive approach to maintaining organization-wide compliance. By identifying potential problems early, you can take steps to reduce their negative impact on your organization, staff, and the patients you serve. Risk assessment results also aid in the proper allocation of compliance resources, strengthen your organization's compliance program, and guide in developing your organization's annual work plan.

Specifically, a comprehensive and ongoing effective risk assessment program allows you to:

Meet the expectations of government agencies.

The Department of Justice, OIG, Centers for Medicare and Medicaid Services (CMS), and other regulatory and accrediting bodies expect healthcare organizations to conduct regular risk assessment. If your organization is charged with criminal wrongdoing or a civil false claim violation, risk assessment can be considered a mitigating factor. Further, annual risk assessment is a common requirement of corporate integrity agreements. U.S. sentencing guidelines for prosecutors state that organizations shall periodically assess the risk of criminal conduct and shall take appropriate steps to design, implement, or modify each component of the compliance program to reduce the risk of criminal conduct identified through this process.

Prevent or reduce penalties for noncompliance.

By identifying weaknesses and correcting your conflict of interest disclosure practices, you can avoid potential violations of the Stark Law and Anti-Kickback Statute. More recently, the Patient Protection and Affordable Care Act implemented new requirements for insurance, Medicaid, and more. Another recent regulation is the 21st Century Cures Act, which includes provisions to increase transparency for patients. Healthcare organizations must provide patients with convenient, unrestricted access to their health information.

Reduce legal risk and improve patient safety and care quality.

Regularly conducting risk assessment improves your healthcare organization's ability to prevent lawsuits and, if they do arise, defend against the allegations. For example, improper provider privileging can lead to negligent privileging lawsuits when patients are harmed by physicians who lack the appropriate training and experience to perform a procedure. By implementing well-documented credentialing and privileging practices that follow accreditation guidelines (e.g., The Joint Commission, National Committee for Quality Assurance, etc.), you can protect patients and prevent liability in the event of patient harm.

Armed with reasons why risk assessment should be a part of your compliance program, where do you start? symplr guides our customers along the following four main steps in the risk assessment process.

4 steps to conduct effective risk assessment

1. Define the scope

Consider starting with small, periodic assessments instead of broad, infrequent ones. By limiting the scope initially, you can expand it with follow-up activities as you uncover any problems—or shift the focus as needed. To define your scope, answer: What? Where? Who? When? How?

What area(s) will you assess to gauge compliance?

Topical areas for review can be recurring or timely, based on regulatory or accreditation updates or hot topics (e.g., the Anti-Kickback Statute and Stark Law). Or you may prioritize areas that previous audits have indicated are problematic for your organization. One example is claim denials for specific diagnoses, resulting in significant repayment liability.

Consider the following:

Source	What to look for
Federal healthcare program requirements	CMS relaxed credentialing, privileging, and telehealth requirements to meet the care coverage demands of COVID-19. Under Emergency Protocol, many providers were granted disaster or emergency privileges—temporary privileges that will terminate when the national emergency ends. Ensure those providers are re-credentialed, re-privileged, and re-enrolled when their temporary privileges expire.
Misconduct reports	Look for issues (e.g., improper billing practices) taken from your organization's incident reports, patient complaints, surveys (e.g., patient, employee, provider satisfaction), and/or calls received from the organization's hotline.
Claim denials/audit results	Examine previous audit reports for improvement recommendations. Analyze your claim denials to identify problem areas. For example, if one department had many claims denied due to lack of medical necessity, examine policies and procedures related to determining medical necessity.

OIG Work Plans and updates	Starting in 2022 the OIG will audit Medicare Part B bills, looking for duplicate Medicare professional fee billing by both the critical access hospital (CAH) and healthcare provider. In this case, your risk assessment would be a review/audit of Medicare Part B bills that include services delivered by healthcare providers who are included under the CAH's Optional (Elective) Payment Method (and thus prohibited from billing the Part B Medicare Administrative Contractor for outpatient services delivered at the CAH).
OIG Fraud Alerts	In November 2021, the OIG issued a fraud alert regarding speaker programs sponsored by pharmaceutical and medical device companies. Based on its fraud and abuse investigations, the OIG concluded that payments to speakers and attendees (in the form of free meals) are often used to induce (or are received in return for) ordering or prescribing items paid for by federal healthcare programs, violating the Anti-Kickback Statute. Your risk assessment would focus on payments and non-monetary compensation received by physicians and other healthcare providers from drug/medical device companies, that may constitute a conflict of interest and violate the Anti-Kickback Statute and Stark Law.
New or updated federal/state laws	The 21st Century Cures Act includes provisions to increase transparency for patients. Healthcare organizations must provide patients with convenient, unrestricted access to their health information. As of April 5, 2021, healthcare providers must meet certain mandated criteria to ensure patients can obtain their electronic health information (EHI) as requested, without interference (i.e., no information blocking). Healthcare providers must identify security risks (via a HIPAA security risk analysis and the NIST Cybersecurity Framework) and examine their security policies and responses to risks. Ensure your clinics are safeguarding protected health information (PHI) when sharing that information with patients via a variety of apps.

Where will the assessment focus?

Determine the organization(s), site(s), and department(s) your risk assessment will target. If you're examining the same risk area in multiple locations or departments throughout your enterprise, use the same assessment tool for each site to arrive at an even comparison of risk.

Who will participate?

Involve multiple individuals at various levels of the organization, depending on the topical area of focus. Clearly identify and communicate their roles. Apprise key stakeholders—senior leaders, the board, and all affected departments and hospital committees—of the risk assessment's goals and objectives. Individuals/departments commonly involved in a risk assessment, for example, are:

- Risk assessment lead (e.g., compliance officer, audit director, risk manager)
- Appropriate department manager(s) and staff
- Internal auditor
- Legal
- Risk assessment committee
- Outside consultants (if necessary)

When will you conduct the assessment?

Keeping in mind that the risk assessment will involve individuals and functions organization wide, establish a flexible assessment schedule. Include target completion dates and expectations for each phase of the assessment (e.g., information gathering, remediation, reporting), and share the expected timeline with participants.

How will you conduct the assessment?

In planning your risk assessment, develop a flexible, comprehensive framework for gathering and measuring data. Use interviews, surveys or questionnaires, document reviews (e.g., bills, conflict of interest disclosures, policies/procedures, prior audits and surveys, community data, etc.), or other means. In other words, use all resources at your disposal when creating questions. Regarding survey design, consider using closed-ended questions: The results are easier to compare, and answers are easier to code and statistically analyze.

Address what methodology you'll use to conduct the assessment, with the goal to identify, classify, and prioritize risks found. Choose a system for classifying or labeling the severity level, ideally one that provides a scale to indicate the threat level. For example:

- Low, moderate, high
- Green, yellow, red
- A numeric ranking

Document the expected outputs (i.e., how will you relay the methodology and results).

2. Conduct the risk assessment

Conduct the assessment according to your planned framework and methodology. Within the focus area under review, prioritize findings that will have the biggest impact on your organization and therefore have the greatest need for remediation and focus. Beyond the anticipated risk severity level, consider and rate these factors for findings:

Likelihood of (re)occurrence

- Improbable
- Remote
- Occasional
- Frequently
- All the time

Impact of occurrence

- Minimal/negligible
- Slight
- Moderate
- Critical/serious
- Catastrophic

Apply the criteria you use to collect data consistently across all risk assessment areas. Document all steps taken and maintain all associated documentation.

Communication throughout the assessment process is key: Instruct participants on how best to provide evidence to support their responses (e.g., policy, education agenda, audit report) . Keep leaders and the assessment participants apprised of progress and setbacks.

3. Manage identified risks

Once the data is in, review the results to understand the nature of the identified risks and to determine their significance. Determine how to respond to each identified risk:

- Accept the risk. This should be the exception, not the rule. Document your decision-making process on lower-risk areas so you can revisit them or be prepared for an audit.
- Defer corrective action. For lower-priority risks, you may choose to delay remediation.
- Take corrective action now to reduce your risk. Start with the highest priority risks, or areas where your organization is most vulnerable.

Once the risk assessment has concluded, the job isn't complete until the areas where risk is rated the highest are mitigated using a corrective action plan (CAP). Develop and implement your CAP using these questions, to start:

- What resources will we need to most effectively reduce the risks?
- Do we need to draft new policies, or can we modify existing policies?
- How will we communicate changes in policy, procedure, or process to employees?
- Are there gaps in employee training that we can correct through the CAP?

Consider including one or several of these steps in your CAP:

- Educating/training staff
- Writing or revising policies and procedures
- Enforcing disciplinary procedures
- Implementing or increasing auditing and monitoring processes
- Using compliance software to identify and resolve potential risks (e.g., conflicts of interest)

As in the risk assessment, document all steps taken during remediation, and maintain all associated documentation.

Continue to audit and monitor the identified risk areas, both formally and informally, to ensure the CAP worked and staff are following the new procedures. Don't discontinue your follow-up after you initiate the CAP. Regulations and risks change frequently, so it's important to continue monitoring risk areas regularly.

4. Report the results

You must report the results of your risk assessment and corrective action plan to key stakeholders, particularly senior management and the board. The OIG, in particular, holds an organization's executive leaders and governing board members ultimately responsible for compliance.

Beyond reporting to organizational leadership, share your assessment results with the managers, staff, and others involved in the process—or potentially with all employees—for educational purposes and to foster a culture of compliance.

Include the following in your final report:

- The risks assessed
- The methodology(ies) for data gathering
- The resources used (e.g., who participated, how information was gathered)
- How the identified risks were rated/prioritized
- A summary of actions taken to mitigate the risk
- A description of the plan for preventing the risks in the future (i.e., your CAP)

Leverage technology for risk assessment

Last but not least, leverage technology to hone your risk assessment strategy. Managing compliance is an around-the-clock endeavor, and healthcare enterprises need a scalable solution to address ever-changing regulations, improve healthcare quality and safety, mitigate financial risk, and keep patients safe. Use a web-based solution to provide workflows and alerts for every level and role—and to gain real-time views into compliance to make timely decisions along the governance, risk, and compliance (GRC) continuum.

Your risk management software should make it easy to assess risk status, manage investigations and incident reporting, and conduct surveys and audits—so you can do more with fewer resources. With everyone working together on mitigating risk, your organization will be better positioned to support a complete culture of compliance and safety.

symplr Compliance offers risk assessment management as a part of our powerful and flexible platform. We provide the single source of truth software, tools, and unique expert content you need to uncover areas of risk and manage the remediation process enterprise wide.

symplr Compliance's Risk Assessment Management module provides a clear picture of your organization's risk status in real time. The module includes a comprehensive attorney-curated library of content with question sets relevant to the Anti-Kickback Statute and Stark Law, the 21st Century Cures Act, OIG updates, and more than 13,000 content questions across most departments.

Hospital Collection Effort for Medicare Bad Debt

Applicable to all hospital settings

As of July 2020

Question Text	Citation
Is the hospital reviewing at least annually whether it is properly reporting bad debts to Medicare and all Medicare bad debt expenses claimed, to ensure that the hospital's procedures are in accordance with applicable Federal and State statutes, regulations, guidelines and policies?	OIG Compliance Program Guidance for Hospitals (II)(A)(6)
Does policy and procedure define bad debt as the amounts considered to be uncollectible from accounts and notes receivable that were created or acquired in providing services?	42 CFR 413.89(b)(1)
Does policy and procedure establish that a bad debt must meet the following criteria to be allowable: (1) the debt must be related to covered services and derived from deductible and coinsurance amounts; (2) the provider must be able to establish that reasonable collection efforts were made; (3) the debt was actually uncollectible when claimed as worthless; and (4) sound business judgment established that there was no likelihood of recovery at any time in the future?	42 CFR 413.89(e); [Pub.15-1 Ch. 3 s.308
Does policy and procedure establish that to be considered a reasonable effort, the hospital's effort to collect Medicare deductible and coinsurance amounts must be similar to the effort the hospital puts forth to collect comparable amounts from non-Medicare patients?	Pub.15-1 Ch. 3 s.310

Question Text	Citation
Do the hospital's reasonable collection efforts involve the issuance of a bill on or shortly after discharge or death of the beneficiary to the party responsible for the patient's personal financial obligations; as well as other actions such as subsequent billings, collection letters and telephone calls or personal contacts with this party which constitute a genuine, rather than a token, collection effort?	Pub.15-1 Ch. 3 s.310
Does policy and procedure establish that if the hospital uses a collection agency, the hospital must refer all uncollected patient charges of like amount to the agency without regard to class of patient?	Pub.15-1 Ch. 3 s.310(A)
Does the hospital document its collection effort in the patient's file by, for example, copies of the bill(s), follow-up letters, reports of telephone and personal contact, etc.?	Pub.15-1 Ch. 3 s.310(B)
Does policy and procedure establish that if a collection agency obtains payment of an account receivable, the full amount collected must be credited to the patient's account and the collection fee charged to administrative costs?	Pub.15-1 Ch. 3 s.310.1
Does policy and procedure establish that if after reasonable and customary attempts to collect a bill, the debt remains unpaid more than 120 days from the date the first bill is mailed to the beneficiary, the debt may be deemed uncollectible?	Pub.15-1 Ch. 3 s.310.2

Question Text	Citation
Does policy and procedure establish that until the hospital's reasonable collection effort (including the use of a collection agency as well as in-house efforts) has been completed, even if that is more than 120 days due to the debt remaining with a collection agency, a Medicare bad debt may not be deemed as uncollectible?	MLN Matters SE0824 Revised, Clarification of Medicare Bad Debt Policy Related to Accounts at a Collection Agency (May 2018) p.1
Does policy and procedure establish that if the hospital determines a patient is indigent, based on the standards established at Pub. 15-1 Ch.3 s.312, and that there have been no improvements in the beneficiary's financial condition, the debt may be deemed uncollectible without taking collection efforts?	Pub.15-1 Ch. 3 s.312
Does policy and procedure establish that the amounts uncollectible from specific beneficiaries are to be charged off as bad debt in the accounting period in which the accounts are deemed to be worthless?	42 CFR 413.89(f); Pub.15-1 Ch. 3 s.314
Does policy and procedure establish that if an amount previously written off as a bad debt and allocated to the Medicare program is recovered in a subsequent accounting period, the income therefrom must be used to reduce the cost of beneficiary services for the period in which the collection is made?	42 CFR 413.89(f); Pub.15-1 Ch. 3 s.316
Does policy and procedure establish that the allowable Medicare bad debt reimbursement is calculated as 65 percent of the uncollectible amount for hospitals, but varies based on provider type?	42 CFR 413.89(h)(1)(v)

Question Text	Citation
Is auditing conducted to ensure that the hospital has appropriate and reasonable mechanisms in place regarding beneficiary deductible or copayment collection efforts and has not claimed as bad debts any routinely waived Medicare copayments and deductibles (which waiver would also constitute a violation of the anti-kickback statute)?	OIG Compliance Program Guidance for Hospitals (II)(A)(6)
Is billing staff trained on the Medicare requirements addressing proper collection of patient debts and steps to take when a debt is determined to be uncollectible and reportable to Medicare as bad debt?	MLN Matters SE0824 Revised, Clarification of Medicare Bad Debt Policy Related to Accounts at a Collection Agency (May 2018) p.1

Advanced Care Planning Services: Compliance with Medicare Requirements

Applicable to physician groups, clinics, federally qualified health centers, and other types of non-hospital, non-long term care settings

As of June 2020

Question Text	Citation
Does policy and procedure define voluntary Advance Care Planning (ACP) as a face-to-face service between the physician (or other qualified health care professional) and a patient to discuss the patient's health care wishes if they become unable to make decisions about their care?	"MLN Fact Sheet, Advance Care Planning (August 2019), p. 2; 80 FR 70886, 70955 (November 16, 2015)"
Does policy and procedure establish that the patient does not need to complete an advance directive in order to bill ACP codes?	MLN Fact Sheet, Advance Care Planning (August 2019), p. 2; CMS Frequently Asked Questions about Billing the Physician Fee Schedule for Advance Care Planning Services (July 14, 2016), p.2
Does policy and procedure establish that Medicare pays for ACP as either an optional element of a patient's Annual Wellness Visit (AWV) or a separate Medicare Part B medically necessary service?	Pub. 100-02 Ch. 15 s.280.5.1; MLN Matters 9271: Advance Care Planning (ACP) as an Optional Element of an Annual Wellness Visit (AWV) (January 2016), p. 2; MLN Fact Sheet, Advance Care Planning (August 2019), p. 2
Does policy and procedure establish that there are no place-of-service limitations on ACP services, ACP services can be provided in facility and non-facility settings, and Medicare does not limit ACP services to a particular physician specialty?	MLN Fact Sheet, Advance Care Planning (August 2019), p. 3; CMS Frequently Asked Questions about Billing the Physician Fee Schedule for Advance Care Planning Services (July 14, 2016), p. 1; 80 Fed. Reg. 70886, 70957

Question Text	Citation
Does policy and procedure establish that CMS does not require a specific diagnosis to bill the ACP codes, and that the provider should report a condition for which the beneficiary is being counseled, an ICD-10-CM code to reflect an administrative examination, or a well exam diagnosis when furnished as part of the AWV?	MLN Fact Sheet, Advance Care Planning (August 2019), p. 3; CMS Frequently Asked Questions about Billing the Physician Fee Schedule for Advance Care Planning Services (July 14, 2016), p.3
Does policy and procedure establish that Medicare waives the coinsurance and the Medicare Part B deductible for ACP when it is: (1) provided on the same day as a covered AWV; (2) furnished by the same provider as a covered AWV; and (3) billed with modifier -33 (Preventive Services)?	Pub. 100-04 Ch. 18 s.140.8; MLN Matters 9271: Advance Care Planning (ACP) as an Optional Element of an Annual Wellness Visit (AWV) (January 2016), p. 2; MLN Fact Sheet, Advance Care Planning (August 2019), p. 4; CMS Frequently Asked Questions about Billing the Physician Fee Schedule for Advance Care Planning Services (July 14, 2016), p.2
Does policy and procedure establish that if the AWV is denied for exceeding the once-per-year limit, Medicare can still make the ACP payment with CMS applying the deductible and coinsurance to the ACP service?	Pub. 100-04 Ch. 18 s.140.8; MLN Matters 9271: Advance Care Planning (ACP) as an Optional Element of an Annual Wellness Visit (AWV) (January 2016), p. 2; MLN Fact Sheet, Advance Care Planning (August 2019), p. 4
Does policy and procedure establish that the deductible and coinsurance does apply when ACP is provided outside the covered AWV?	MLN Matters 9271: Advance Care Planning (ACP) as an Optional Element of an Annual Wellness Visit (AWV) (January 2016), p.2; MLN Fact Sheet, Advance Care Planning (August 2019), p. 4
Does policy and procedure establish that when a patient elects to get ACP services outside of the AWV, the physician should notify the patient that Part B cost sharing applies as it does for other physicians' services?	MLN Fact Sheet, Advance Care Planning (August 2019), p. 2; CMS Frequently Asked Questions about Billing the Physician Fee Schedule for Advance Care Planning Services (July 14, 2016), p.3

Question Text	Citation
Does policy and procedure establish that there is no limit on the number of times ACP can be reported for a given patient in a given period?	MLN Fact Sheet, Advance Care Planning (August 2019), p. 2; CMS Frequently Asked Questions about Billing the Physician Fee Schedule for Advance Care Planning Services (July 14, 2016), p.1
Is auditing conducted to ensure proper use of CPT code 99497 (Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; first 30 minutes, face-to-face with the patient, family members(s), and/or surrogate); and code 99498 (each additional 30 minutes)?	Pub. 100-04 Ch. 18 s.140.8; MLN Fact Sheet, Advance Care Planning (August 2019), p. 3; CMS Frequently Asked Questions about Billing the Physician Fee Schedule for Advance Care Planning Services (July 14, 2016), p.1
Does policy and procedure establish that the ACP codes may be billed on the same day and during the same visit as an Evaluation and Management code, with the exception of certain critical care services, or they may be billed as stand alone codes?	CMS Frequently Asked Questions about Billing the Physician Fee Schedule for Advance Care Planning Services (July 14, 2016), p.2-3
Is auditing conducted to ensure that when billing the ACP service multiple times, documentation is made of the change in the patient's health status and/or wishes regarding their end-of-life care?	MLN Fact Sheet, Advance Care Planning (August 2019), p. 2; CMS Frequently Asked Questions about Billing the Physician Fee Schedule for Advance Care Planning Services (July 14, 2016), p.1

Question Text	Citation
Does the provider consult its Medicare Administrative Contractor (MAC) regarding documentation requirements for ACP services? Does policy and procedure establish that at a minimum, documentation of ACP services should include an account of the discussion with the beneficiary (or family members and/or surrogate) regarding the voluntary nature of the encounter; documentation indicating the explanation of advance directives (along with completion of those forms, when performed); who was present; and the time spent in the face-to-face encounter? Are appropriate staff trained on ACP documentation requirements?	CMS Frequently Asked Questions about Billing the Physician Fee Schedule for Advance Care Planning Services (July 14, 2016), p.2
Does policy and procedure establish that ACP is reimbursable when performed by a physician or a non-physician provider (NPP), including nurse practitioners, physician assistants and clinical nurse specialists?	MLN Fact Sheet, Advance Care Planning (August 2019), p. 2; CMS Frequently Asked Questions about Billing the Physician Fee Schedule for Advance Care Planning Services (July 14, 2016), p.2
Does policy and procedure establish that the billing physician or NPP of the ACP service should manage, participate and meaningfully contribute to the provision of the services, in addition to providing a minimum of direct supervision?	MLN Fact Sheet, Advance Care Planning (August 2019), p. 4; CMS Frequently Asked Questions about Billing the Physician Fee Schedule for Advance Care Planning Services (July 14, 2016), p.2
Does policy and procedure establish that ACP services provided by non-physician or non-NPP members of the provider are reimbursable if performed "incident to" the services of the billing practitioner, including a minimum of direct supervision?	"CMS Frequently Asked Questions about Billing the Physician Fee Schedule for Advance Care Planning Services (July 14, 2016), p.2"
Does policy and procedure establish that Medicare beneficiaries (or their legal proxies when applicable) should be given a clear opportunity to decline to receive ACP services?	"CMS Frequently Asked Questions about Billing the Physician Fee Schedule for Advance Care Planning Services (July 14, 2016), p.2; 80 FR 70886, 70957 (November 16, 2015)"

Nursing Homes' Compliance w/Facility-Initiated Discharge Requirements

Applicable to Long Term Care organizations

As of November 2020

Question Text	Citation
In response to CMS waivers related to COVID-19, does policy and procedure allow the facility to temporarily transfer its COVID-19 positive resident(s) to another facility, such as a COVID-19 isolation and treatment location, with the provision of services "under arrangements?"	"Long Term Care Facilities (Skilled Nursing Facilities and/ or Nursing Facilities): CMS Flexibilities to Fight COVID-19 (November 4, 2020), p.7"
Does policy and procedure establish that for transfers of COVID-19 residents "under arrangement," if the facility is the transferring facility, it does not need to issue a formal discharge and should bill Medicare normally for each day of care and reimburse the provider that accepted its resident(s) during the emergency period?	"Long Term Care Facilities (Skilled Nursing Facilities and/ or Nursing Facilities): CMS Flexibilities to Fight COVID-19 (November 4, 2020), p.7"
Does policy and procedure establish that if the facility does not intend to provide services "under arrangement," the COVID-19 isolation and treatment facility is the responsible entity for Medicare billing purposes?	"Long Term Care Facilities (Skilled Nursing Facilities and/ or Nursing Facilities): CMS Flexibilities to Fight COVID-19 (November 4, 2020), p.7"

Question Text	Citation
Does policy and procedure establish that under the COVID waiver the facility can transfer or discharge residents to another long term care facility for the following cohorting purposes: (1) transferring residents with symptoms of a respiratory infection or confirmed diagnosis of COVID-19 to another facility that agrees to accept each specific resident, and is dedicated to the care of such residents; (2) transferring residents without symptoms of a respiratory infection or confirmed to not have COVID-19 to another facility that agrees to accept each specific resident, and is dedicated to the care of such residents to prevent them from acquiring COVID-19, as well as providing treatment or therapy for other conditions as required by the resident's plan of care; or (3) transferring residents without symptoms of a respiratory infection to another facility that agrees to accept each specific resident to observe for any signs or symptoms of a respiratory infection over 14 days?	"Long Term Care Facilities (Skilled Nursing Facilities and/or Nursing Facilities): CMS Flexibilities to Fight COVID-19 (November 4, 2020), p.7"
Does policy and procedure establish that the facility must receive confirmation (in writing or verbal) that the receiving facility agrees to accept the resident to be transferred or discharged?	"Long Term Care Facilities (Skilled Nursing Facilities and/or Nursing Facilities): CMS Flexibilities to Fight COVID-19 (November 4, 2020), p.8"
Does policy and procedure establish that if the confirmation from the receiving facility is verbal, the facility must document the date, time, and person at the receiving facility that communicated agreement?	"Long Term Care Facilities (Skilled Nursing Facilities and/or Nursing Facilities): CMS Flexibilities to Fight COVID-19 (November 4, 2020), p.8"

Question Text	Citation
Does policy and procedure establish that a resident may not be transferred or discharged from the facility unless: (1) it is necessary for the resident's welfare and the resident's needs cannot be met in the facility; (2) it is appropriate because the resident's health has improved sufficiently and facility services are no longer needed; (3) the safety of individuals in the facility is endangered due to the clinical or behavioral status of the resident; (4) the health of individuals in the facility would otherwise be endangered; (5) the resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare/Medicaid) a facility stay; or (6) the facility ceases to operate?	42 CFR 483.15(c)(1)(i)
Does policy and procedure establish that the facility may not transfer or discharge the resident while an appeal is pending, pursuant to 42 CFR 431.230, when a resident exercises his or her right to appeal a transfer or discharge notice from the facility pursuant to 42 CFR 431.220(a)(3), unless the failure to discharge or transfer would endanger the health or safety of the resident or other individuals in the facility; and that the danger that failure to transfer or discharge would pose must be documented?	42 CFR 483.15(c)(1)(ii); 42 CFR 431.230; 42 CFR 431.220(a)(3)
Does policy and procedure require that when the transfer or discharge is made under any of the circumstances specified at 42 CFR 482.15(c)(1)(i), documentation is made in the resident's medical record and appropriate information is communicated to the receiving health care institution or provider?	42 CFR 483.15(c)(2); 42 CFR 483.15(c)(1)(i)

Question Text	Citation
Is auditing conducted to ensure that documentation of resident transfer in the resident's medical record includes the basis for the transfer; and in the case of a transfer due to the facility not being able to meet the resident's needs, the specific need(s) that could not be met, facility attempts to meet the needs, and the service available at the receiving facility to meet the needs?	42 CFR 483.15(c)(2)(i)
Does policy and procedure require that if the resident is transferred or discharged due to the facility not being able to meet the resident's needs or because the resident's health has improved sufficiently so the resident no longer needs the facility's services, that the required medical record documentation must be made by the resident's physician; and if transfer or discharge is due to the safety or health of individuals in the facility being endangered that the medical record documentation must be made by a physician?	42 CFR 483.15(c)(2)(ii)(A)
Does policy and procedure require that before the facility transfers or discharges a resident, it must notify the resident and the resident's representative(s) of the transfer or discharge and the reasons for the move, including all items identified at 42 CFR 483.15(c)(5), in writing and in a language and manner they understand, and send a copy of the notice to a representative of the Office of the State Long-Term Care Ombudsman? (This requirement that notice must be provided before transfer or discharge is temporarily waived by CMS per the COVID-19 waivers. Notice must be provided as soon as practicable.)	42 CFR 483.15(c)(3)(i); 42 CFR 483.15(c)(3)(iii); 42 CFR 483.15(c)(5); Long Term Care Facilities (Skilled Nursing Facilities and/or Nursing Facilities): CMS Flexibilities to Fight COVID-19 (November 4, 2020), p.7

Question Text	Citation
Does policy and procedure require that before the facility transfers or discharges a resident, it must record the reasons for the transfer or discharge in the resident's medical record? (This requirement in regard to notice being provided before transfer or discharge is temporarily waived by CMS per the COVID-19 waivers. Notice must be provided as soon as practicable.)	"42 CFR 483.15(c)(3)(ii); Long Term Care Facilities (Skilled Nursing Facilities and/or Nursing Facilities): CMS Flexibilities to Fight COVID-19 (November 4, 2020), p.7"
Does policy and procedure establish that if transfer is due to a significant change in the resident's condition, but not an emergency requiring an immediate transfer, the facility must, prior to any action, conduct and document the appropriate assessment to determine if revisions to the care plan would allow the facility to meet the resident's needs?	Pub. 100-07 App.PP s.483.15(c), (c)(1), (c)(2)
Does policy and procedure establish that a resident's declination of treatment does not constitute grounds for discharge, unless the facility is unable to meet the needs of the resident or protect the health and safety of others?	Pub. 100-07 App.PP s.483.15(c), (c)(1), (c)(2)
Does policy and procedure establish that residents who are sent to the emergency room must be permitted to return to the facility, unless the resident meets one of the criteria under which the facility can initiate discharge?	Pub. 100-07 App.PP s.483.15(c), (c)(1), (c)(2)
Does policy and procedure establish, unless an exception applies, that the notice of transfer or discharge must be made by the facility at least 30 days before the resident is transferred or discharged?	42 CFR 483.15(c)(4)(i)

Question Text	Citation
Does policy and procedure require that notice of transfer or discharge must be made as soon as practicable before transfer or discharge when the safety or health of the individuals in the facility would be endangered; the resident's health improves sufficiently to allow a more immediate transfer or discharge; an immediate transfer or discharge is required by the resident's urgent medical needs; or a resident has not resided in the facility for 30 days? (This requirement that notice must be provided before transfer or discharge is temporarily waived by CMS per the COVID-19 waivers. Notice must be provided as soon as practicable.)	"42 CFR 483.15(c)(4)(ii); Long Term Care Facilities (Skilled Nursing Facilities and/or Nursing Facilities): CMS Flexibilities to Fight COVID-19 (November 4, 2020), p.7"
Does the written notice of transfer or discharge include: (1) reason for transfer or discharge; (2) effective date of transfer or discharge; (3) location to which the resident is transferred or discharged; (4) a statement of the resident's appeal rights, including the name, address (mailing and email), and telephone number of the entity which receives such requests; and information on how to obtain an appeal form and assistance in completing the form and submitting the appeal hearing request; (5) the name, address (mailing and email) and telephone number of the Office of the State Long-Term Care Ombudsman; and, as appropriate, (6) the mailing and email address and telephone number for the agency responsible for the protection and advocacy of individuals with developmental disabilities or a mental disorder? (The inclusion of the reason for transfer or discharge and a statement of the resident's appeal rights and how to obtain an appeal form and assistance in completing it have been temporarily waived by CMS per the COVID-19 waivers.)	"42 CFR 483.15(c)(5); Long Term Care Facilities (Skilled Nursing Facilities and/or Nursing Facilities): CMS Flexibilities to Fight COVID-19 (November 4, 2020), p.7"

Question Text	Citation
Does policy and procedure establish that if the information in the notice of transfer or discharge changes prior to effecting the transfer or discharge, the facility must update the recipients of the notice as soon as practicable once the updated information becomes available?	42 CFR 483.15(c)(6)
Does policy and procedure establish that in situations where the facility has decided to discharge the resident while the resident is still hospitalized, the facility must send a notice of discharge to the resident and resident representative, and must also send a copy of the discharge notice to a representative of the Office of the State Long-Term Care Ombudsman?	Pub. 100-07 App.PP s.483.15(c)(3)-(c)(6), (c)(8)
Does policy and procedure establish that when a resident is temporarily transferred on an emergency basis to an acute care facility, this type of transfer is considered to be a facility-initiated transfer and a notice of transfer must be provided to the resident and resident representative as soon as practicable, according to 42 CFR 483.15(c)(4)(ii)(D)?	Pub. 100-07 App.PP s.483.15(c)(3)-(c)(6), (c)(8); 42 CFR 483.15(c)(4)(ii)(D)
Does the facility provide and document sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility, with orientation provided in a form and manner that the resident can understand?	42 CFR 483.15(c)(7)

Question Text	Citation
Does policy and procedure require that prior to transferring a resident to a hospital or the resident going on therapeutic leave, the facility must provide written information to the resident or resident representative that specifies: (1) the duration of the state bed-hold policy, if any, during which the resident is permitted to return and resume residence in the facility; (2) the reserve bed payment policy in the state plan, if any; (3) the facility's policies regarding bed-hold periods, permitting a resident to return; and (4) the information specified in 42 CFR 483.15(e)(1)? (This requirement is temporarily waived by CMS per the COVID-19 waivers.)	42 CFR 483.15(d)(1); 42 CFR 483.15(e)(1); Long Term Care Facilities (Skilled Nursing Facilities and/or Nursing Facilities): CMS Flexibilities to Fight COVID-19 (November 4, 2020), p.7
Does policy and procedure permit residents to return to the facility after they are hospitalized or placed on therapeutic leave?	42 CFR 483.15(e)(1)
Does policy and procedure establish that if the facility determines that a resident who was transferred with an expectation of returning to the facility cannot return to the facility, the facility must follow the discharge requirements established at 42 CFR 483.15(c)?	42 CFR 483.15(e)(1)(ii); 42 CFR 483.15(c)

Medicare Part D Payments for Transmucosal Immediate-Release Fentanyl Drugs

Applicable to Managed Care organizations

As of May 2020

Question Text	Citation
Does policy and procedure establish that transmucosal immediate-release fentanyl (TIRF) medicines are indicated only to manage breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for underlying persistent cancer pain; with the only exception being for Actiq, and its generic equivalents, which are approved for cancer patients 16 years and older?	"Transmucosal Immediate Release Fentanyl (TIRF) Products Risk Evaluation and Mitigation Strategy (REMS): Education Program for Prescribers and Pharmacists, p.3 https://www.tirfremsaccess.com/TirfUI/rems/pdf/education-and-ka.pdf
Is auditing conducted to ensure that the sponsor maintains current and accurate records of the receipt and disposition of TIRF medicines, due to their being Schedule II controlled substances (high potential for abuse; currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions; and abuse of these drugs may lead to severe psychological or physical dependence)?	"Controlled Substances Act, 21 U.S.C. s. 812(b)(2); Transmucosal Immediate Release Fentanyl (TIRF) Products Risk Evaluation and Mitigation Strategy (REMS): Education Program for Prescribers and Pharmacists, p.4 https://www.tirfremsaccess.com/TirfUI/rems/pdf/education-and-ka.pdf
Does the sponsor have a reasonable and appropriate drug utilization management program that meets the requirements of 42 CFR 423.153(b) and addresses the overutilization of frequently abused drugs?	42 CFR 423.153(a); 42 CFR 423.153(b); 42 CFR 423.153(f)

Question Text	Citation
As part of the drug management program, has the sponsor implemented a point of sale prior authorization edit for TIRF medicines to determine appropriate coverage? Does policy and procedure require verification of opioid tolerance with each prescription of a TIRF medicine that is written and dispensed?	42 CFR 423.153(f)(3) NOTE TO: Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties on SUBJECT: Advance Notice of Methodological Changes for Calendar Year (CY) 2015 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2015 Call Letter (February 21, 2014) p. 125
Is auditing conducted to ensure that prescribers document a patient's opioid tolerance concurrently with each prescription of a TIRF medicine for outpatient use?	Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to strengthen agency's safety requirements aimed at mitigating risks associated with transmucosal immediate-release fentanyl products, (March 2019)
Does policy and procedure require the sponsor's prescribers, pharmacies, distributors and members to enroll in the TIRF Risk Evaluation and Mitigation Strategy (REMS) access program in order to prescribe, dispense or receive drugs in the TIRF medicines class?	Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to strengthen agency's safety requirements aimed at mitigating risks associated with transmucosal immediate-release fentanyl products, (March 2019)
Does policy and procedure require the sponsor to evaluate the impact of the REMS on member access to their TIRF medicines as part of required periodic assessments of the REMS?	Questions and Answers: FDA approves a class Risk Evaluation and Mitigation Strategy (REMS) for transmucosal immediate-release fentanyl (TIRF) medicines (July 2015)

Question Text	Citation
Do policies and procedures address measures to help limit abuse of TIRF medicines, including: proper assessment of patients; safe prescribing practices; periodic re-evaluation of therapy; proper dispensing and storage; retention of detailed records of prescribing information, including quantity, frequency, and renewal requests; retention of signed TIRF REMS Access Patient-Prescriber Agreement Forms; and informing patients/caregivers to protect against theft and misuse of TIRF medicines?	Transmucosal Immediate Release Fentanyl (TIRF) Products Risk Evaluation and Mitigation Strategy (REMS): Education Program for Prescribers and Pharmacists, p.4 https://www.tirfremsaccess.com/TirfUI/rems/pdf/education-and-ka.pdf
Has the sponsor established quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use of TIRF medicines in accordance with 42 CFR 423.153(c)?	42 CFR 423.153(c)
Does the sponsor ensure that prescribers, pharmacists and patients are educated on the risks and safe use of TIRF medicines and their potential for misuse, abuse, addiction and overdose?	Immediate Release Fentanyl (TIRF) Products Risk Evaluation and Mitigation Strategy (REMS): Education Program for Prescribers and Pharmacists, p.2; OIG Data Brief, Medicare Part D Beneficiaries at Serious Risk of Opioid Misuse or Overdose: A Closer Look, OEI-02-19-00130 (May 2020) p. 11

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