



Medicare Advantage FDR Compliance Program Requirements Guide

Section 1: Introduction

First Tier, Downstream, and Related Entities

Quartz depends on our contracted providers and other vendors/contractors to help us meet the needs of our membership in accordance with Medicare Advantage (MA) and Medicare Prescriptions Part D program requirements. These individuals and entities are considered First Tier, Downstream, and Related Entities (“FDRs”). FDRs are individuals or entities that provide administrative or health care service functions relating to the Medicare Advantage contract with CMS. FDRs are a vital part of the Medicare Advantage program and have specific responsibilities under Medicare guidelines.

Quartz is committed to conducting business with integrity. Our Medicare compliance program helps to:

- Prevent, detect, and correct fraud, waste and abuse (FWA)
- Make ensure we comply with all applicable laws, rules, and regulations
- Reinforce our commitment to compliance

You may find specific requirements in this guide

As a Quartz Medicare Advantage FDR, you must satisfy specific Medicare compliance program requirements. We described these requirements in this guide. The Code of Federal Regulations (CFR) outlines these requirements in 42 C.F.R. §§422.503(b)(4)(vi) and 423.504(b)(4)(vi), and they are also defined by CMS in the Compliance Program Guidelines in Chapter 21 of the [Medicare Managed Care Manual](#) and Chapter 9 of the [Prescription Drug Benefit Manual](#).

It is important that FDRs follow these requirements?

You received this guide because Quartz has identified you as a first-tier entity. This means you must comply with these requirements. The purpose of this Medicare Advantage FDR Compliance Program Requirements Guide is to help FDRs in understanding and meeting their compliance obligations under its contract(s) with a Medicare Advantage Plan Sponsor.

Section 2: What does FDR mean?

FDR stands for first tier, downstream and related entities. If you perform an administrative or health care service function on behalf of Quartz Medicare Advantage business, then you are classified as an FDR.

Examples of FDRs include, providers contracted to provide services to our Medicare Advantage members, sales agents, vendors providing administrative services for our Medicare Advantage members/products and delegated entities contracted to make decisions on our behalf for our Medicare Advantage members/products. We utilize current CMS definitions to define First Tier, Downstream and Related Entities:

First Tier Entity is any party that enters into a written agreement, acceptable to CMS, with an MA organization or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare eligible individual under the MA program or Part D program.

Downstream Entity is any party that enters into a written agreement, acceptable to CMS, with persons or entities involved with MA benefit or Part D benefit, below the level of the arrangement between an MA organization or applicant or a Part D plan sponsor or applicant and a First Tier Entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

Related Entity means any entity that is related to the MA organization or Part D sponsor by common ownership or control and:

1. Performs some of the MA organization or Part D plan sponsor's management functions under contract or delegation;
2. Furnishes services to Medicare enrollees under an oral or written agreement; or
3. Leases real property or sells material to the MA organization or Part D plan sponsor at a cost of more than \$2,500 during a contract period.

See 42 CFR §§ 422.500 and 423.501 for more information.

FDRs that provide health care services

The Medicare compliance requirements described in this guide apply to health care providers contracted with our Medicare network. This includes physicians, hospitals and other provider types. Below are the reasons why:

- MA regulations and CMS rules state that providers contracted with the Quartz to provide health care services are "First Tier Entities."
- Chapter 21 § 40 of the Medicare Managed Care Manual lists health care services as an example of the types of functions that a third party can perform that relates to an MA organization's contract with CMS. This would give third parties "First Tier Entity" status. So, these CMS compliance requirements apply to providers that deliver health care services.
- CMS provides a chart in Chapter 21 § 40 of the Medicare Managed Care Manual, showing that entities provided health care services and hospital groups are First Tier Entities. If we contract with a hospital group and don't have a direct contract with the group's hospital and other providers, the hospital and providers are considered Downstream Entities. This means the hospital group:
 - Is a First-Tier Entity,
 - Must comply with CMS compliance requirements in this guide,
 - Must-ensure its Downstream Entities comply too.

FDRs that provide administrative services

Medicare compliance program requirements also apply to entities we contract with to perform administrative service functions for our MA, and Part D contracts with CMS. Some examples of administrative functions include: claims processing, agents, broker organizations, pharmacies, and other individuals, entities, vendors or suppliers contracted to provide administrative and/or health care services for our MA plans. You can find more information available in [Chapter 21 § 40 Sponsor Accountability for and Oversight of FDRs of the Medicare Managed Care Manual](#), including the Stakeholder Relationship Flow Charts.

Section 3: FDR Medicare Compliance Program and Attestation Requirements

Quartz is committed to conducting business practices in compliance with ethical standards, contractual obligations, and all applicable state and federal laws, regulations and rules. Quartz's compliance commitment extends to its FDRs.

It's important our FDRs comply with these requirements and follow applicable laws, rules and regulations. Although we contract with FDRs to provide administrative and/or health care services for our Medicare Advantage plans, we're ultimately responsible for fulfilling the terms and conditions of our contract with CMS and for meeting applicable Medicare program requirements. Our FDRs are responsible for complying with applicable Medicare requirements, and they must-ensure that their Downstream Entities also comply with all applicable laws and regulations, as well as the requirements in this guide.

Medicare Compliance Program Requirements

As an FDR, you-must comply with Medicare compliance program requirements including, but not limited to:

- Complete general compliance and FWA training/education
- Distribute-Code of Conduct/compliance program policies
- Complete exclusion list screenings
- Maintain record retention
- Make employees aware of reporting mechanisms
- Report FWA and compliance concerns to us
- Report and request to use offshore operations
- Fulfill specific federal and state compliance obligations
- Monitor-and audit-First Tier, Downstream and Related Entities

Medicare compliance requirements apply to all employees (including temporary employees and volunteers), governing board members, and contractors providing a health or administrative services relating to Quartz Medicare Advantage plans.

This guide summarizes the Medicare compliance program requirements. Please review it to make sure you have internal processes to support compliance with these requirements each calendar year. Please reference the "Toolbox of Resources for FDRs" located at the end of this guide to help you meet these requirements.

What may happen if FDRs fail to comply with Medicare Compliance Program requirements?

If our FDRs fail to meet Medicare compliance program requirements, Quartz will handle noncompliance on a case-by-case basis. Our response to noncompliance depends-on the severity of the issue, it may lead to:

- Retraining
- Development of a corrective action plan (CAP)
- Increased monitoring, or
- Termination of your contract and relationship with us

Confirm completion of Requirements

You must keep evidence of your compliance with Medicare compliance requirements for no less than 10 years. This evidence may include employee training records and completed exclusion list screenings.

Each year, an authorized representative from your organization must attest to your compliance with the Medicare compliance program requirements described in this guide. This must be someone who has responsibility, directly or indirectly, for all:

- Employees
- Contracted personnel
- Providers/practitioners
- Vendors who provide health care and/or administrative services for our Medicare Advantage plans.

This could be your compliance officer, chief medical officer, practice manager/administrator, an executive officer or someone in a similar position.

A Medicare Advantage FDR Annual Compliance Attestation will be sent to all FDRs annually. The Medicare Advantage FDR Annual Compliance Attestation and other FDR related documents are available on the Quartz Medicare Advantage FDR Compliance webpage [here](#).

You may be asked to provide documentation of compliance

In addition to completing an annual attestation, Quartz and/or CMS may request that you provide documentation of your compliance with these Medicare compliance program requirements. This is for monitoring and auditing purposes.

A. Distribute general compliance and FWA Training/Education

As a First Tier Entity, your organization must provide general compliance and FWA training to all employees and downstream entities assigned to provide administrative and/or health care services for Quartz's Medicare Advantage business.

CMS no longer requires FDRs to complete its Medicare Parts C and D General Compliance and Combating Medicare Parts C and D Fraud, Waste, and Abuse Training. Instead, you may complete your own version of general compliance and FWA training specific to your organization's needs.

When must training/education be completed?

Required training/education must be completed:

- Within 90 days of initial hire or the effective date of contracting
- When materials are updated
- Annually thereafter

You must maintain evidence of training completion for ten years after conducting the training. Evidence of completion may be in the form of certificates, attestations, training logs or other means determined by the FDR to best signify fulfillment of these obligations. If training logs or standardized reports are utilized as documentation of completion, they should include:

- Employee names
- Dates of hire
- Name of training topic
- Date of completion
- Test score (if captured)

This [sample training log](#) provides a way to document your employees' completion of training. You can also send this to your Downstream Entities to use for their employees' training completion. FDRs can find the training requirements in Chapter 21 §§ 50.3.1 and 50.3.2. of the Medicare Managed Care Manual.

Who needs to complete the training?

Not every employee needs to take the training. Your organization should make the determination as to which individuals in the organization provide an administrative or health care service to Quartz Medicare Advantage plans. Below are examples of critical roles that CMS requires to fulfill the training requirements:

- Senior administrators or managers directly responsible for the FDR's contract (for example, senior vice president, departmental managers, chief medical or pharmacy officer);
- Individuals directly involved with establishing and administering Quartz's Medicare Advantage formulary and/or medical benefit coverage policies and procedures;
- Individuals involved with decision-making authority on behalf of Quartz Medicare Advantage (for example, clinical decisions, coverage determinations, appeals and grievances, enrollment/disenrollment functions, processing of pharmacy or medical claims);
- Reviewers of beneficiary claims and services submitted for payment; or
- Individuals with job functions that place the FDR able to commit significant noncompliance with CMS program requirements or health care FWA.

Not sure which employees at your organization should take the training? Just review this [table](#). If you still have questions about which employee positions within your organization should be required to take the training, please contact us at QuartzFDR@Quartzbenefits.com

Exception to the FWA training requirement.

The only exception to the FWA training requirement is if you or your organization is "deemed" to have met the FWA training and education requirements through one or both of the following:

- Enrollment into Medicare Part A or B of the Medicare program
- Accreditation as a supplier of Durable Medical Equipment, Prosthesis, Orthotics, and Supplies (DMEPOS) supplier

You can find the requirements and information about deemed status in:

- 42 CFR § 422.503(b)(4)(vi)(C) for MA
- 42 CFR § 423.504(b)(4)(vi)(C) for Part D
- Medicare Managed Care Manual, Chapter 21, §50.3

Those parties deemed to have met the FWA training through enrollment into the CMS Medicare are still obligated to complete general compliance training. Evidence that you or your organizations "deemed" status must be made available to Quartz and/or CMS upon request.

B. Distribute Code of Conduct and Compliance Program Policy Distribution

The “Code of Conduct” is a set of key principles and expectations by which an organization operates, and defines the underlying framework for compliance policies and procedures. The Code of Conduct and compliance program policies established by Quartz describe our organization’s expectations that all employees conduct themselves in an ethical manner; that issues of noncompliance and potential FWA are reported through appropriate mechanisms; and that reported issues will be investigated, addressed, and corrected. The code of conduct communicates to employees of your organization and those of your Downstream Entities that compliance is everyone’s responsibility.

As a Quartz Medicare Advantage FDR, you must provide either Quartz’s [Code of Conduct](#) and [applicable compliance program policies](#) or your own comparable code of conduct and applicable compliance program policies to all employees and Downstream Entities. The written compliance policies and code of conduct must contain all the elements set forth in Section 50.1 and its subsection of Manual, Chapter 21, and articulate the entity’s commitment to comply with federal and state laws, ethical behavior and compliance program operations. You must also retain evidence of the distribution of the code of conduct for 10 years.

FDRs must distribution the code of conduct/applicable policies:

- Within 90 days of hire or effective date of contracting
- When there are updates to the code of conduct
- Annually thereafter.

You can find these code of conduct requirements at:

- 42 CFR § 422.503(b)(4)(vi)(A) for MA
- 42 CFR § 5423.504(b)(4)(vi)(A) for Part D
- Medicare Managed Care Manual, Chapter 21 § 50.1

C. Complete Exclusion List Screenings

Federal law prohibits Medicare, Medicaid and other federal health care programs from paying for items or services furnished or prescribed by a person or entity excluded from participation in federal programs.

So before hiring or contracting, and monthly thereafter, each FDR must check the exclusion lists from the Office of Inspector General (OIG) and U.S. General Services Administration (GSA) to confirm your employees and Downstream Entities aren’t excluded from participating in federally funded programs.

FDRs can utilize the websites below to complete the required exclusion list screening:

- [Office of Inspector General \(OIG\) List of Excluded Individuals and Entities \(LEIE\)](#)
- [General Services Administration \(GSA\) System for Award Management \(SAM\)](#)

You must conduct screenings before hiring or contracting, and monthly thereafter for each:

- Employee
- Temporary employee
- Volunteer
- Consultant
- Governing board member

You must also maintain for 10 years evidence that you have checked the OIG and GSA exclusion lists. You can utilize logs, reports, or other records to document that you or your organization has screened each employee and Downstream Entity.

No matter what process you use to perform these required checks, the documentation to demonstrate compliance with this requirement should clearly identify:

- the name of the entity/individual checked;
- the exclusion/debarment list that was checked;
- the date the check was performed;
- the results of the check, and
- any actions taken if sanctioned individuals or entities were identified.

Quartz is also required to check these exclusion lists prior to hiring or contracting with any new employee, temporary employee, volunteer, consultant, governing body member or FDR, and monthly after that. Quartz is unable to check these exclusion lists for your employees and Downstream Entities. So, to make sure we comply with this CMS requirement, FDRs must confirm that their permanent and temporary employees and Downstream Entities that provide administrative and/or health care services for our Medicare Advantage plans are not on either of these exclusion lists.

FDRs must take immediate action if an employee or downstream entity is on the exclusion list

If any of your employees or downstream entities are on one of these exclusion lists, you must immediately remove them from work directly or indirectly related to Quartz Medicare Advantage plans and notify us right away. If your organization becomes excluded, Quartz must be notified immediately.

These exclusion lists requirements are noted in:

- § 1862(e)(1)(B) of the Social Security Act
- 42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)
- 422.752(a)(8)
- 423.752(a)96)
- 1001.1901
- Medicare Managed Care Manual, Chapter 21, § 50.6.8.

The following reporting resources are available:

- Kelly Skifton, AVP Compliance & Government Regulatory Ops: (608) 881-8151
- Kristie Meier, Director, Deputy General Counsel and Compliance Officer: (608) 643-1402

Confidential Compliance Reporting:

- Local Compliance Hotline: (608) 644-3495
- Toll-free Compliance Hotline: (844) 492-2996
- Email: Submit an electronic form to compliance.hotline@quartzbenefits.com

Anonymous Compliance Reporting:

- Mail: 840 Carolina Street, Sauk City, WI 53583

D. Record Retention

FDRs must maintain evidence of training completion

FDRs must comply with Medicare laws, regulations and CMS requirements (See, 42 CFR § 422.504 (i)(4)(v)), and agree to audits and inspection by CMS and/or its designees and will cooperate, assist, and provide information as requested, and will maintain records a minimum of 10 years.

CMS requires FDRs to maintain evidence of training completion, distribution of the code of conduct, and OIG and GSA exclusion screening for a minimum of 10 years. This requirement is noted in the Medicare Managed Care Manual Ch. 21 §50.3.2

FDR responsibilities relating to auditing by CMS or its designee

CMS has discretionary authority to perform audits under 42 CFR 422.504(e)(2) and 423.505(e)(2), which specify the right to audit, evaluate, or inspect any books, contracts, medical records, patient care documentation, and other records of Medicare Advantage Plan Sponsor FDRs that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract or as the Secretary of Health and Human Services may deem necessary to enforce the contract.

FDRs and Quartz must provide records to CMS or its designee. FDRs and Quartz should cooperate in allowing access as requested. Failure to comply may result in a referral of Quartz and/or FDR to law enforcement and/or implementation of other corrective actions including intermediate sanctioning in line with 42 CFR Subpart O. (See, Medicare Managed Care Manual, Chapter 21, § 50.6.11)

E. Report FWA and Compliance Concerns to Quartz

Reporting is critical for the prevention, detection, and correction of fraud, waste and abuse. There are a number of ways to report suspected or detected noncompliance or potential FWA. You'll find them on Quartz's [Compliance Reporting Poster](#).

You can use this poster to post in your organization and it can also be distributed to employees or Downstream Entities to advise them how to report Medicare program compliance concerns and/or FWA to Quartz without fear of intimidation or retaliation against anyone who reports suspected misconduct.

CMS requires Quartz to have a system in place to receive, record, respond to and track compliance questions or reports of suspected or detected noncompliance or potential FWA from employees, member of the governing body, enrollees and FDRs and their employees. These reporting requirements are noted in the Medicare Managed Care Manual Ch. 21 § 50.4.2

Compliance concerns and suspected or actual violations of noncompliance related to Medicare programs are taken very seriously. FDRs should train employees on the importance of reporting violations of noncompliance and FWA. As an FDR that contacts with Quartz, you must ensure all your employees and those of any of your Downstream and Related Entities are informed of how to report compliance concerns and suspected misconduct. Quartz will perform an internal investigation of each concern after your organization reports an incident.

FDRs must create reporting mechanisms for their organization that is anonymous and does not lead to intimidation or retaliation; or you can refer your employees and Downstream Entities to report compliance issues to Quartz’s Compliance Hotline. Quartz has safeguards in place to protect any individual or organization who reports actual or suspected noncompliance or fraud, waste and abuse from intimidation and retaliation.

Committed to Quartz’s compliance program is Kelly Skifton, Assistant Vice President Compliance & Government Regulatory Operations. Questions or concerns for Kelly and/or her Medicare Advantage compliance team can be sent to QuartzFDR@Quartzbenefits.com

F. Report and Request use of Offshore Operations and CMS Reporting

FDRs are required to notify the Companies if you plan to use an offshore subcontractor

Medicare Advantage Organizations that work with offshore subcontractors (including first tier, downstream and related entities) to perform Medicare related work that uses beneficiary protected health information (PHI) are required to provide CMS with specific offshore subcontractor information and complete an attestation regarding protection of beneficiary PHI. (CMS Memo dated August 26, 2008: Offshore Subcontractor Data Module in HPMS)

- CMS considers MA organizations and PDP Sponsors to be “contractors” with respect to CMS for the purposes of delivering Medicare Part C and Part D benefits. The term “subcontractor” refers to any organization that a sponsor contracts with to fulfill or help fulfill requirements in their Part C and/or Part D contracts. Subcontractors include all first tier, downstream, and/or related entities.
- The term “offshore” refers to any country that is not one of the fifty United States or one of the United States Territories (American Samoa, Guam, Northern Marianas, Puerto Rico, and Virgin Islands). Examples of countries that meet the definition of offshore include: Mexico, Canada, India, Germany, and Japan.

To help make sure Quartz complies with applicable federal and state laws, rules and regulations, you are required to notify us in advance of your intent to use an offshore subcontractor(s) or before employing offshore staff for a function Quartz has asked you to perform.

Notify us immediately if you plan to use an offshore entity

If you perform services offshore or use an offshore subcontractor to perform services using involving the receipt, processing, transferring, handling, storing or accessing of Quartz member protected health information (PHI), you must complete the “[Offshore Services Attestation](#)” found on Quartz Medicare FDR Compliance webpage under Resources, and submit to the Compliance Department utilizing the methods listed on the attestation. You must obtain approval from Quartz prior to use of an offshore subcontractor. An authorized Compliance Department representative will review your request and will respond to you in writing.

G. Monitor and Audit of First Tier and Downstream Entities

Quartz is responsible for the lawful and compliant administration of the Medicare Parts C and D benefits under our contract with CMS. CMS requires that we create a strategy to monitor and audit our First-Tier Entities to ensure they follow all applicable laws and regulations, and to ensure that our First-Tier Entities are monitoring the compliance of their Downstream Entities with which they contract.

If you choose to contract with another organization to provide administrative and/or health care services for Medicare Advantage plans, you are required to make sure that these Downstream Entities abide by all laws and regulations that apply to you as a First-Tier Entity.

As a First-Tier Entity, you are responsible for the compliance of your downstream entities. You or your organization should create a procedure for auditing and monitoring Downstream Entities. You must conduct necessary oversight to ensure that your employees and Downstream Entities comply with all applicable laws and regulations, retain evidence of completion, implement CAPs or take disciplinary actions, as necessary, to prevent recurrence of noncompliance with applicable laws.

FDRs should expect monitoring and audits

Monitoring and auditing of first tier entities for compliance program requirements must include an evaluation to confirm that the first-tier entities are applying appropriate compliance program requirements to downstream entities with which the first-tier contracts.

Quartz will monitor and periodically audit FDRs for all services or responsibilities delegated to the FDR. FDRs must cooperate and contribute in these monitoring and auditing activities. FDRs must routinely monitor and/or intermittently audit Downstream Entities if they are performing services for Medicare Advantage plans. Below is a list of possible documents that may be required of your entity:

- Evidence of completion of General Compliance FWA training
- Distribution of Code of Conduct and compliance policies
- Education of reporting compliance violations and potential FWA
- Exclusion list screenings
- Offshore subcontracting information
- Monitoring and Auditing of downstream entities
- CAPs for downstream entities

If Quartz determines that an FDR is noncompliant with any of the requirements in this guide, we'll require the FDR to develop a CAP and submit it to Quartz's Compliance Department.

Monitoring and auditing requirements are referenced in:

- 42 CFR § 422.503(b)(4)(vi)(F) for MA
- 42 CFR § 423.50(b)(4)(vi)(F) for Part D
- Medicare Managed Care Manual, Chapter 21, §50.6.6

Questions or Concerns

For compliance questions or concerns, you can email us at QuartzFDR@Quartzbenefits.com

Toolbox of Resources for FDRs

Requirement/Resource	Time Frame
Code of Conduct and Compliance Policies	
<p>Don't have your own Code of Conduct? Feel free to distribute our Code of Conduct to your employees.</p>	<p>90 days of hire or effective date of contract and annually thereafter</p>
<p>Compliance Policies These applicable compliance program policies provide more detail about our Medicare compliance program.</p>	
Exclusion List Screenings	
<ul style="list-style-type: none"> • Complete OIG exclusion list screening • Complete GSA's SAM exclusion list screening. <p>Maintain evidence of exclusion verification. Evidence may include screen prints of the exclusion results, exclusion reports, etc. Evidence must clearly show the name of the individual/entity checked; date of hire; what exclusion list was screened; date the source was verified, and results of the check.</p>	<p>Before hire/contracting and monthly thereafter for your employees and Downstream Entities.</p>
Record Retention	
<p>Maintain records and supporting documentation for a period of 10 years and furnish evidence of the above to Quartz and CMS upon request.</p>	<p>Retain evidence for a minimum 10 years</p>
Reporting Mechanisms	
<p>How do I report noncompliance or potential FWA to Quartz? This Compliance Reporting Poster provides ways for reporting issues that impact Quartz. Feel free to share this throughout your organization so that your employees know how to report concerns. This poster can also be distributed to any of your Downstream Entities or Related Entities.</p>	<p>Issues of noncompliance or FWA must be reported immediately</p>
Monitoring and Oversight	
<p>Downstream Entity oversight You must conduct oversight of your Downstream Entities. This can be done by requesting attestations from your Downstream Entities to monitor their compliance.</p>	<p>Annual (high risk) Periodic (medium and low-risk)</p>
Offshore Services Attestation	
<p>FDR's who use an offshore subcontractor to perform services that involve the processing, transferring, handling, storing or accessing of Medicare member PHI, must complete this Offshore Services Attestation and return the completed form to Quartz at QuartzFDR@Quartzbenefits.com.</p>	
Other tools	
<p>Chapter 21 of the Medicare Managed Care Manual Chapter 9 of the Prescription Drug Benefit Manual</p>	<p>Intermittent when there are questions or concerns regarding compliance</p>
FDR FAQs (Frequently Asked Questions)	
<p>If you have questions that we didn't answer in this guide, review our FDR Frequently Asked Questions located under "Resources" here</p>	

Compliance

Do the Right Thing. Compliance Begins with You.

**You are obligated to report
any compliance issues.**

The following compliance resources are available –

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- Kelly Skifton**..... (608) 881-8151
AVP, Compliance and Government Regulatory Ops
- Kristie Meier**..... (608) 643-1402
Director, Deputy General Counsel - Compliance Services

Confidential Compliance Reporting

-
- Local**..... (608) 644-3495
- Toll-free**..... (844) 492-2996
- Email**Submit an electronic form to
compliance.hotline@quartzbenefits.com

Anonymous

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- Mail**..... 840 Carolina Street
Sauk City, WI 53583

The Quartz logo is displayed in a bold, red, sans-serif font.