HEALTHCARE REGULATORY ROUND-UP - Episode #29

Rural Emergency Hospital Program: Proposed Rule

July 13, 2022

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WE ARE AN INDEPENDENT MEMBER OF HLB—THE GLOBAL ADVISORY AND ACCOUNTING NETWORK

Introductions

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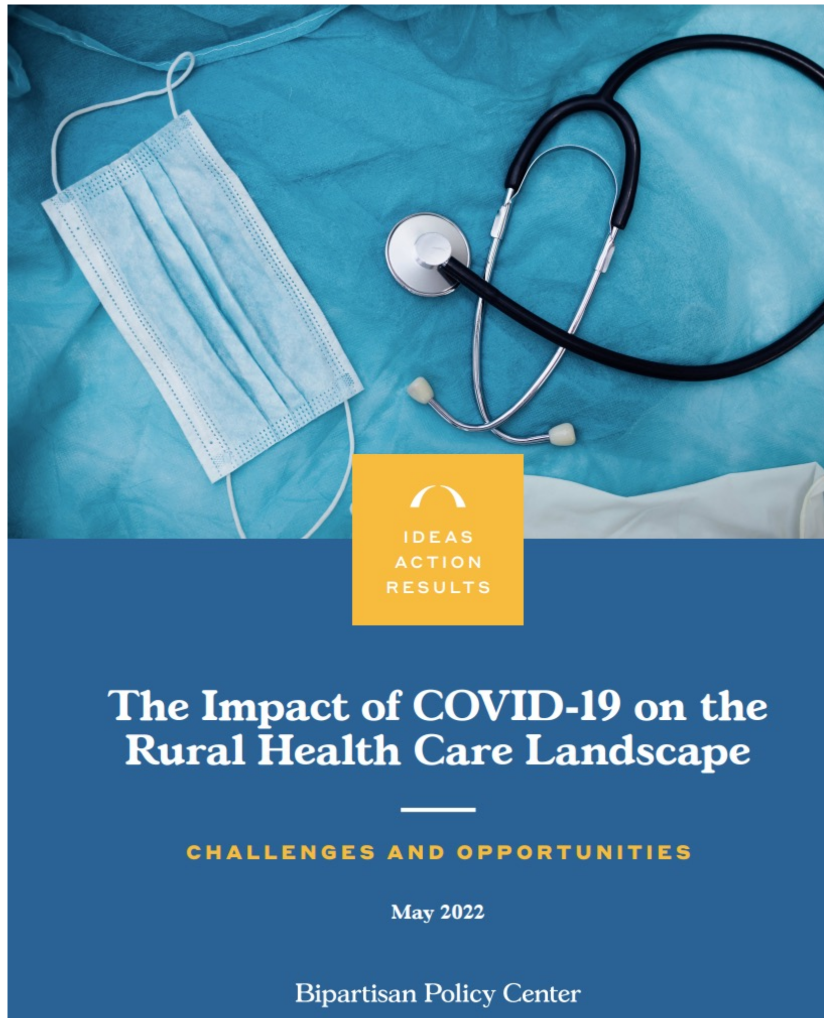

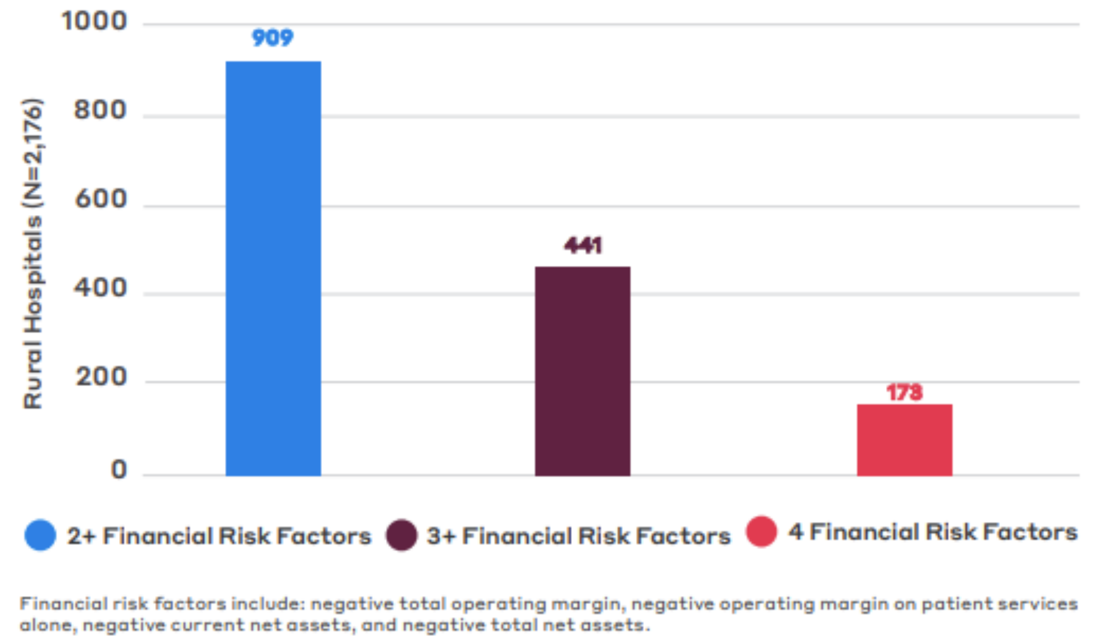

Available at https://bipartisanpolicy.org/download/?file=/wp-content/uploads/2022/05/BPC-Medicare-Rural-EmerHsp_R02.pdf

Consolidated Appropriations Act of 2021

PYA

- Create new category of Medicare payment for ***rural emergency hospital (REH) services***
- Addresses the following:

1. Eligibility
2. Timing
3. Services
4. Conditions of Participation
5. Quality reporting
6. Payment
7. Application Process

Implementing Regulations

PYA

- Proposed REH Conditions of Participation (CoPs) released June 30
  - Also includes new proposed CAH CoPs
  - **Comments due August 29**
- REH payment methodology and quality reporting requirements to be addressed in 2023 Hospital OPPS proposed rule

AGENCY: HHS-CMS **RIN:** 0938-AU82 **Status:** Pending Review
TITLE:CY 2023 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1772)
STAGE: Proposed Rule **ECONOMICALLY SIGNIFICANT:** Yes
RECEIVED DATE: 05/04/2022 **LEGAL DEADLINE:** Statutory

42 CFR 485.502 – Definitions

PYA

- Cannot provide inpatient services (except distinct-part unit licensed as SNF to provide post-acute services)
- Must provide emergency department services and observation care; may provide “other outpatient medical and health services as specified by the Secretary”
  - Annual per patient length of stay does not exceed 24 hours
  - Despite providers’ concerns relating to transfer delays, CMS does “not anticipate that the REH would be at risk for exceeding the statutory annual per patient average length of stay ….”

485.506 and 508 - Eligibility

PYA

- As of December 27, 2020, the facility was:
  - CAH
  - PPS hospital with ≤50 beds "located in a county (or equivalent unit of local government) that is considered rural"
  - PPS hospital with ≤50 beds "that was treated as being located in a rural area that has had an active reclassification from urban to rural status as specified in [42 CFR § 412.103] as of December 27, 2020."

  *Is REH an option for facility that has closed **since** December 27, 2020?*
- Must be located in state that provides for REH licensure **and** must be licensed or approved by appropriate state agency
  - Kansas is only state with statute that provides for such licensure (K.S.A. 65-481 to 65-488)

Proposed Conditions of Participation

PYA

42 CFR 485.508 Compliance with Federal, state, and local laws and regulations

485.510 Governing body and organizational structure

485.512 Medical staff

485.514 Provision of services

485.516 Emergency services

485.518 Laboratory services

485.520 Radiologic services

485.522 Pharmaceutical services

485.524 Additional outpatient medical and health services

485.526 Infection prevention and control and antibiotic stewardship programs

485.528 Staffing and staff responsibilities

485.530 Nursing services

485.532 Discharge planning

485.534 Patient’s rights

485.536 Quality assessment and performance improvement program

485.538 Agreements

485.540 Medical records

485.542 Emergency preparedness

485.544 Physical environment

485.546 Skilled nursing facility distinct part unit

REH CoP 485.516 - Emergency Services

PYA

- As required by the CAA, CoP requires REH to meet CAH CoPs regarding –
  - 24-hour availability of emergency services
  - Equipment, supplies, and medication
  - Blood and blood products
  - Personnel
  - Coordination with emergency response systems

Emergency Services - Personnel

PYA

- Physician or non-physician practitioner on call and immediately available by telephone or radio contact, and available on site within 30 minutes
  - Extended to 60 minutes if located in frontier area or remote location (as defined by state rural health plan) or if state has formally determined 30 minutes is not feasible
- RN may satisfy personnel requirement *on temporary basis* if –
  - Located in frontier area or remote location
  - State's governor submits temporary request to CMS
  - REH submits documentation of inability to provide physician/non-physician practitioner coverage
- To change these requirements for REHs, have to change CAH CoP for emergency services

EMTALA

PYA

- CAA amends EMTALA statute (42 USC 1395dd) by including REH in the definition of “hospital” for purposes of that statute
- CMS has not proposed any changes to EMTALA implementing regulations (42 CFR 489.24) or Appendix V of the State Operations Manual
  - Regulation defines “hospital” to include CAH (but not REH)
- “One commenter … recommended EMTALA waivers for REHs to diver patients to other hospitals if they require a higher level of care than the REH is able to provide. However, the statutory requirements for REHs do not allow an EMTALA waiver.”

REH CoP 485.520 - Radiologic Services

<u>42 CFR 482.26 Condition of participation: Radiologic services.</u>

The hospital must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.

(a) ***Standard: Radiologic services.*** The hospital must maintain, or have available, radiologic services according to needs of the patients.

(b) ***Standard: Safety for patients and personnel.*** The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

(1) Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.

(2) Periodic inspection of equipment must be made and hazards identified must be promptly corrected.

(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

(4) Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.

(c) ***Standard: Personnel.***

(1) A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

(2) Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.

(d) ***Standard: Records.*** Records of radiologic services must be maintained.

(1) The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.

(2) The hospital must maintain the following for at least 5 years:

(i) Copies of reports and printouts.

(ii) Films, scans, and other image records, as appropriate.

<u>42 CFR 485.635(b)(3) Radiology Services.</u>

Radiology services furnished by the CAH are provided by personnel qualified under State law, and do not expose CAH patients or personnel to radiation hazards.

REH CoP 485.522 - Pharmaceutical Services

42 CFR 482.25 Condition of participation: Pharmaceutical services

The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

(a) *Standard: Pharmacy management and administration.* The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

(1) A full-time, part-time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

(2) The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.

(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.

(b) *Standard: Delivery of services.* In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

(1) All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.

(2)

(i) All drugs and biologicals must be kept in a secure area and locked when appropriate.

(ii) Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.

(iii) Only authorized personnel may have access to locked areas.

(3) Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

(4) When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.

(5) Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.

(6) Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital's quality assessment and performance improvement program.

(7) Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

(8) Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff.

(9) A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs.

42 CFR 485.623(b) Standard: Maintenance. The CAH has housekeeping and preventive maintenance programs to ensure that - … (3) drugs and biologics are appropriately stored

42 CFR 485.635(a)(3): [A CAH must have patient care policies, including]

(iv) rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept to the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.

(v) Procedures for reporting adverse drug reactions and errors in the administration of drugs.

REH CoP 485.524 - Additional Outpatient Services

PYA

- REH may provide “items and services that are commonly furnished in a physician’s office or at another entry point into the health care delivery system that include, but are not limited to, radiology, laboratory, outpatient rehabilitation, surgical, maternal health, and behavioral health services.”
  - Provide services based on nationally recognized guidelines and standards of practice
  - Have system for referral to different levels of care, as appropriate
  - Have effective communication system between REH and patient and family to ensure REH is responsive to their needs and preferences
  - Have established relationships with hospitals having resources/capacity to deliver care beyond the scope of care delivered at REH
  - Have appropriate professional and non-professional personnel at each outpatient location based on scope and complexity of services
  - Additional standards for surgical services and administration of anesthesia

REH CoP 485.536 - Quality Assurance & Performance Improvement

42 CFR 485.641(c) Standard: Governance and Leadership. The CAH's governing body or responsible individual is ultimately responsible for the CAH's QAPI program and is responsible and accountable for ensuring that the QAPI program meets the requirements of paragraph (b) of this section and that:

(1) Clear expectations for safety are communicated, implemented, and followed throughout the CAH.

(2) The QAPI efforts address priorities for improved quality of care and patient safety.

(3) All improvement actions are evaluated and modified as needed.

(4) Adequate resources are allocated for measuring, assessing, improving and sustaining the CAH's performance and reducing risk to patients.

(5) The determination of the number of distinct improvement projects is made annually.

(6) The CAH develops and implements policies and procedures for QAPI that address what actions the CAH staff should take to prevent and report unsafe patient care practices, medical errors, and adverse events.

"[W]e have re-evaluated our proposed requirements to eliminate unnecessary prescriptiveness proposed under paragraph (c)(1) through (6) . . . and are withdrawing those proposed provisions. These changes to the proposal will allow each CAH the flexibility to implement its QAPI program in the most efficient manner for its unique circumstances."

42 CFR 485.536(d) Standard: Executive responsibilities. The REH's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the REH), medical staff, and administrative officials are responsible and accountable for ensuring the following:

(1) That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained.

(2) That the REH-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety; and that all improvement actions are evaluated.

(3) That clear expectations for safety are established.

(4) That adequate resources are allocated for measuring, assessing, improving, and sustaining the REH's performance and reducing risk to patients.

REH CoP 485.538 - Agreements

PYA

- Per statutory requirement, REH must have agreement with at least one Level I or Level II trauma center for referral/transfer of patients requiring emergency medical care beyond REH's capabilities
  - Even if most transfers go elsewhere, such agreement still required
  - No specifications regarding receiving hospital's obligations (EMTALA sufficient?)
  - No provision comparable to CAH rural health network CoP

Other Proposed REH CoPs

PYA

- 485.526 Infection prevention and control and antibiotic stewardship programs
  - Tracks CAH CoP with 2023 proposed changes
- 485.532 Discharge planning
  - Tracks current CAH CoP (effective December 2019)
  - Appropriate to impose same requirements when no admissions?
- 485.534 Patient Rights
  - Tracks proposed CAH CoP

REH Payment – Statutory Provisions

PYA

- 105% applicable OPPS rate (subject to sequestration)
  - SNF PPS rate for distinct-part SNF services (loss of swing bed cost-based reimbursement)
  - Ambulance fee schedule rate for REH-furnished service (loss of cost-based reimbursement if sole provider within 35 miles of facility)
  - Telehealth originating site
  - Maintain provider-based rural health clinic status (maintain cost-based reimbursement?)
  - Physical therapy, occupational therapy, speech language pathology services reimbursed on MPFS, not OPPS (thus, no 5% bump)
- Additional facility payment (same amount for all REHs)
  - Difference between total amount paid to all CAHs in 2019 and amount that would have been paid under PPS rates divided by total number of CAHs in 2019 (about 1,350)
    - Adjust annually by hospital market basket percentage increase
  - Required reporting on actual use of additional facility payment

Outpatient PPS Reimbursement Comparison

State	State Total or Average Value	Rural Non-CAH <101 beds Provider ID (Count)	Total Facility Beds	Total OP PPS Reimb	OP PPS Cost	OP PPS Margin	OP PPS Reimb % of Cost
Illinois	Total	14	899	123,030,329	144,182,378	(21,152,049)	85.27%
Illinois	Average		64	8,787,881	10,298,741	(1,510,861)	85.27%
Kansas	Total	19	1063	75,832,411	89,849,936	(14,017,525)	78.75%
Kansas	Average		56	3,991,180	4,728,944	(737,764)	78.75%
Montana	Total	2	98	25,031,585	30,887,813	(5,856,228)	81.40%
Montana	Average		49	12,515,793	15,443,907	(2,928,114)	81.40%
Nebraska	Total	2	145	24,655,753	33,396,080	(8,740,327)	72.13%
Nebraska	Average		73	12,327,877	16,698,040	(4,370,164)	72.13%
Sample States	Total	37	2,205	248,550,078	298,316,207	(49,766,129)	79.39%
Sample States	Average		60	6,717,570	8,062,600	(1,345,031)	79.39%
					Current Reimb/Cost Ratio		79.39%
					REH OP Adjustment		105%
					Potential Reimb/Cost Ratio		83.36%

Other Payers

PYA

- Medicaid
  - No CMS guidance
  - Eligibility for Medicaid DSH payments?
  - State plan amendments?
  - MCO contracts?
- Medicaid Advantage plans
- Commercial payers

Application Process – Statutory Provisions

- Detailed transition plan listing services the facility will -
  - ✓ Modify
  - ✓ Retain
  - ✓ Discontinue
  - ✓ Add
- Description of the emergency and observation services applicant intends to provide
- Information regarding how applicant intends to use monthly facility payment
- Other information specified by CMS

Evaluating the REH Opportunity

PYA

- Board and community engagement
- Inpatient/outpatient outmigration analysis
- Opportunities for regional collaboration
- Financial analyses

Proposed Changes to CAH CoPs

- 485.610 - Status and Location
- 485.614 - Patient Rights
- 485.631 - Staffing and Staff Responsibilities
- 485.640 - Infection Prevention and Control and Antibiotic Stewardship Programs

CAH CoP 485.610 - Status and Location

PYA

- If not designated as ‘necessary provider,’ CAH must be located more than a 35-mile drive on primary roads (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from hospital or another CAH
  - CMS proposes to define ‘primary roads’ as a numbered Federal highway, including interstates, expressways or any other numbered Federal highway OR a numbered State highways with 2 or more lanes each way

CAH CoP 485.601 - Status and Location

PYA

- 3-year review cycle of distance and location
  - CAHs with no new hospitals within 50 miles = immediate recertification
  - CAHs with new hospitals within 50 miles = prior to recertification, additional review based on distance and the definitions for primary roads and mountainous terrain
    - Those failing to meet regulatory distance and location requirements considered non-compliant
      - Possible enforcement actions

CAH CoP 485.614 - Patient Rights

PYA

- Establish the rights of all patients to receive care in a safe setting and provide protection for a patient's emotional health and safety as well as their physical safety
  - Requirements include –
    - Notify patients of their rights/prompt resolution of grievances
      - Grievance process includes requirement for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate QIO
    - Patient has the right to participate in the development and implementation of their plan of care
      - Compliance with advance directives

CAH CoP 485.614 - Patient Rights

PYA

- Requirements continued –
  - Address privacy and safety – free from all forms of abuse or harassment
  - Adhere to confidentiality of patient records; right of access
  - Adherence to patient visitation rights
    - Requirement for written policies and procedures
    - Inform patients of their visitation rights in advance of furnishing care (if possible)
    - Ensure all visitors enjoy full and equal visitation rights consistent with patient preferences

CAH CoP 485.614 - Patient Rights

PYA

- Requirements continued –
  - Responsibilities for the use of restraint and seclusion
    - Restraint or seclusion may only be used to ensure immediate physical safety of patient, staff member, or others and must be discontinued at the earliest possible time
    - Requirement for staff training on restraints and seclusion
    - Requirement to report deaths association with use of restraint or seclusion
      - Report to CMS no later than close of business on next business day following knowledge of patient's death
      - Includes deaths that occur within 24 hours after patient removed from restraint or seclusion or those within one week if reasonable to assume restraint/seclusion contributed to death

CAH CoP 485.631 - Staffing and Staff Responsibilities

- Unified and integrated medical staff for CAH in multi-facility system
  - Decision approved by medical staff members
  - Unified medical staff has bylaws, rules and requirements to describe processes for self-government, appointment, credentialing, privileging and oversight, as well as peer review policies

CAH CoP 485.640 - Infection Prevention and Control and Antibiotic Stewardship Programs

- Allow for governing body of CAH that is part of system with single governing body that is legally responsible for conduct of two or more hospitals to elect to have unified and integrated programs for all its member facilities (if in accordance with state and local laws)
  - Each facility must be considered in establishing program and have -
    - Qualified individual(s) with expertise in infection prevention and control and antibiotic stewardship responsible for communication of program, implementing and maintaining policies and procedures, and providing staff education/training

Our Next Regulatory Round-Ups

PYA

2023 Medicare Physician Fee Schedule Proposed Rule, Part I – July 21

Conversion Factor, AUC, Telehealth MSSP, Care Management

2023 Medicare Physician Fee Schedule Proposed Rule, Part II – August 3

E/M, Split/Shared Visits, MEI, Behavioral Health, Global Surgical Package, Dental Coverage

2023 Medicare Physician Fee Schedule Proposed Rule, Part III - August 10

Quality Payment Program Update

2023 Hospital OPPS/ASC Proposed Rule – Date TBD

2023 Hospital IPPS, Inpatient Rehab, Inpatient Psych, and SNF Final Rules – Dates TBD

2022 Summer CPE Symposium
What's Hot in Healthcare

2 DAYS | 8 CPEs

JULY 27 & 28 • 11AM – 3:15PM ET

- Summer 2022 Audit & Assurance Updates
- Medicare Margin & Reimbursement Drivers
- Single Audits and COVID-19
- Pricing Transparency: Using the Data
- Total Costs of IT
- Stark Law Value-Based Exceptions
- Clinical Trials Program - New or Expanded Service Line

PYA

How can we HELP?

A national healthcare advisory services firm providing consulting, audit, and tax services