BILLING, CODING, AND COLLECTING FOR INFUSION SERVICES

January 25, 2023

Presented by:

Carine Leslie, RHIA, CCS | Senior Manager | PYA, P.C.

Katie Garmon, MSHA, CPhT, CAC | Manager | PYA, P.C.

Shannon Wiley, JD | Member | Bass, Berry & Sims PLC

BASS BERRY SIMS

AGENDA

- **Billing and Coding for Infusion Services**
  - Infusion Models
  - CPT codes and included services
  - Incident to billing
  - E/Ms
  - Documentation and Claims Rejections
- **Patient Payment Collections**
  - Applicable Laws and Exceptions
  - Advising on Cost and Up Front Collections
  - Financial Assistance programs
  - Payment Plans and Collections

BILLING AND CODING FOR INFUSION SERVICES

BASS BERRY SIMS

FALSE CLAIMS ACT
31 U.S.C. §3729 *ET SEQ.*

Cannot knowingly submit false or fraudulent claims or cause someone else to submit false or fraudulent claims for government reimbursement

"Knowingly" is broad:

1. Actual knowledge
2. Deliberate ignorance
3. Reckless disregard

"Bootstrapping": Anything downstream from an AKS or Stark Law violation is a "false or fraudulent" claim under the FCA

"Whistleblowers" or relators: individuals that file a civil qui tam suit for FCA violations on behalf of themselves and the U.S. government

Civil Penalties:

- $12,537 – 35,076 per claim
- Up to three times the amounts in damages ("treble" damages)

PHYSICIAN / NON-PHYSICIAN PRACTITIONER (NPP) INFUSION CENTER MODEL

- Codes for non-chemotherapy injections and infusions and chemotherapy administration include the following three categories of codes in Current Procedural Terminology (CPT):
  1. Hydration
  2. Therapeutic, prophylactic, and diagnostic injections and infusions (excluding chemotherapy)
  3. Chemotherapy administration

WHAT'S INCLUDED IN INFUSION SERVICES

- If performed to facilitate the infusion or injection, the following services are included and are not reported separately:
  - Use of local anesthesia
  - IV start
  - Access to indwelling IV, subcutaneous catheter, or port
  - Flush at conclusion of infusion
  - Standard tubing, syringes, and supplies
  - Preparation of chemotherapy agent(s)

Note: *Physician work related to these services involves the confirmation of the treatment plan and the provider supervision/nonphysician clinical staff.*

CPT CODES 96365-96379:
Therapeutic, Prophylactic, And Diagnostic Injections and Infusions

- **96365** Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
- **96366** each additional hour (List separately in addition to code for primary procedure)
- **96367** additional sequential infusion of a new drug/substance, up to 1 hour (List separately in addition to code for primary procedure)
- **96368** concurrent infusion (List separately in addition to code for primary procedure)
- **96369** Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); initial, up to 1 hour, including pump set-up and establishment of subcutaneous infusion site(s)
- **96370** each additional hour (List separately in addition to code for primary procedure)
- **96371** additional pump set-up with establishment of new subcutaneous infusion site(s) (List separately in addition to code for primary procedure)
- **96372** Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
- **96373** intra-arterial
- **96374** intravenous push, single or initial substance/drug
- **96375** each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)
- **96376** each additional sequential intravenous push of the same substance/drug provided in a facility (List separately in addition to code for primary procedure)

CPT CODES 96401-96549:
Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration

- **96401** Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic
- **96402** hormonal anti-neoplastic
- **96405** Chemotherapy administration; intralesional, up to and including 7 lesions
- **96406** intralesional, more than 7 lesions
- **96409** intravenous, push technique, single or initial substance/drug
- **96411** intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure)
- **96413** Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
- **96415** each additional hour (List separately in addition to code for primary procedure)
- **96416** initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump
- **96417** each additional sequential infusion (different substance/drug), up to 1 hour (List separately in addition to code for primary procedure)

“INCIDENT TO” BILLING

FEDERAL CONSIDERATIONS: INCIDENT TO BILLING

- Generally Drug is “Incident to” the Physician or NP’s service
- NP’s administration can be “Incident to” the Physician’s Service or Nurse can administer “Incident to” the NP’s service
- 2 Different Concepts

INCIDENT TO BILLING – ADMINISTRATION [NO PHE WAIVER]

- **"Incident to" - Bill Physician's NPI**
  - Direct Supervision - Direct supervision does not mean that the physician must be present in the same room
    - However, the physician must be present in the office suite and immediately available to provide assistance and direction throughout the time the aide is performing services
  - Supervision required even if NP could perform without supervision under state law
  - Can be employee, leased employee, or independent contractor
  - The physician supervising the auxiliary personnel furnishing the services or supplies must have a relationship with the legal entity billing and receiving payment for the services or supplies that satisfies the requirements for valid reassignment
- **"Incident to" – Bill NP's NPI**
  - Same rules as above, but reimbursement is 85% of physician fee schedule; drug reimbursement is not pro rated

INCIDENT TO BILLING – ADMINISTRATION

- This does not mean each occasion of service need also always be the occasion of the actual rendition of a personal professional service by the physician
- Such a service or supply could be considered to be incident to when furnished during a course of treatment where the physician performs an initial service and subsequent services of a frequency which reflect his/her active participation in and management of the course of treatment

INCIDENT TO BILLING – ADMINISTRATION IN THE PUBLIC HEALTH EMERGENCY

- In response to the COVID-19 Public Health Emergency, CMS amended the definition of "Direct Supervision" to include virtual presence through audio/video real-time communications technology (excluding audio-only)
  - This flexibility will expire at the end of the federal Public Health Emergency
- As of writing, the Public Health Emergency is set to expire on April 16, 2023

PROVIDER SUPERVISION REQUIREMENTS

Hospital Outpatients
Including Critical Access Hospital Outpatients

- Effective January 1, 2020, CMS requires, as the minimum level of supervision, **general supervision** by an appropriate physician or non-physician practitioner in the provision of all therapeutic services.
- **"General supervision"** means the definition specified at 42 Code of Federal (CFR) 410.32(b)(3)(i), that is, the procedure or service is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure.

Physician Office/Freestanding Facility

- CMS requires **direct supervision** by an appropriate physician or non-physician practitioner for all therapeutic services.
- **"Direct supervision"** means the definition specified at 42 CFR 410.32(b)(3)(ii), that is, the physician must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

EVALUATION AND MANAGEMENT(E/M) SERVICES

- When a significant separately identifiable E/M is performed, the appropriate E/M code should be reported utilizing modifier 25 in addition to the chemotherapy administration or nonchemotherapy injection and infusion service.
- An E/M can be supported when the service is for:
  - Follow-up of disease process; **or**
  - New problem unrelated to the condition receiving treatment; **or**
  - Symptoms, side effects, adverse treatment reactions, or toxicities of malignancy or treatment.

IDENTIFYING SEPARATE E/M SERVICES

- Significant separately identifiable services are best supported by an intervention:
  - Order for lab/diagnostic services
  - Prescription medication
  - Referral to specialist
  - Treatment modifications
  - Coordination of care, documented as total length of E/M visit (face-to-face and non-face-to-face spent by the provider on the date of service)

PHYSICIAN ORDER REQUIREMENTS

- Name of the patient
- Date and time of the order
- Drug name
- Dose, frequency, and route
- Exact strength or concentration, when applicable
- Quantity and/or duration, when applicable
- Specific instructions for use, when applicable
- Name of the prescriber

BEST PRACTICES FOR INFUSION DOCUMENTATION

Minimum requirements

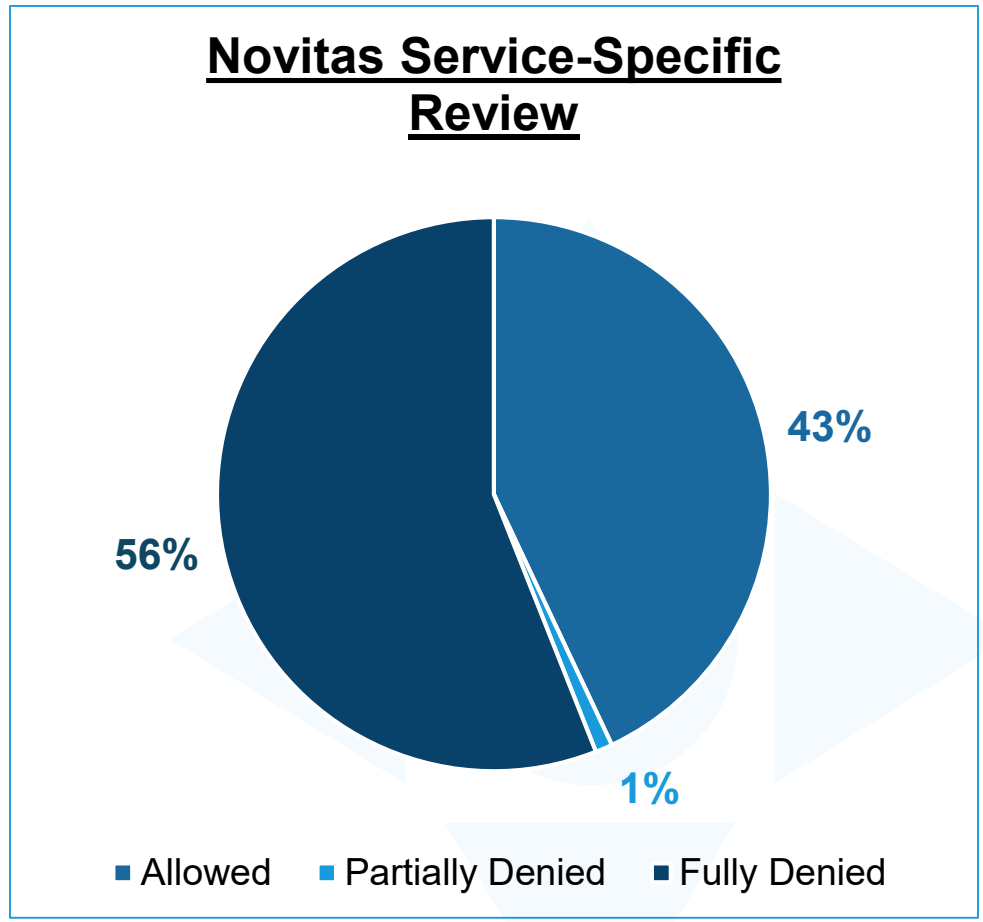
- Drug/substance administered
- Route of administration
- Access site (IV at right antecubital, pro-VAD, etc.)
- Start and stop times
- Rate of administration
- The dose and volume of the drug administered
- The amount of drug wasted or discarded
- ID of the clinician who administered the substance

Additional documentation

- Patient vitals (blood pressure, weight, etc.)
- Patient tolerance of drug/substance
- Adverse outcomes, if applicable
- Evidence that the line was flushed when infusion/injection was complete

NOVITAS POST-PAYMENT REVIEW

- Drugs and biologicals
- Drug Injections (HCPCS J1745) Remicade with associated administration code(s)
  - JH Drug Injection (Remicade) Service Specific Reviews (June 2021 – December 2021)
  - JL Drug Injection (Remicade) Service Specific Reviews (June 2021 - December 2021)



NOVITAS POST-PAYMENT REVIEW (CONT.)

- Top denial/partial denial reasons
  - The most common reasons for denial or partial denials are the following:
    - **Incorrect Coding** – Documentation submitted for review did not support the number of administered units, therefore the claim was changed to reflect the appropriate units administered supported by the documentation.
    - **Insufficient Documentation** – The documentation provided was insufficient to support the services as billed to Medicare. Novitas Medical Review makes multiple attempts to correct these error types before completion of the review. Below are the following denial reasons for insufficient documentation that we were not able to resolve:
      - No response to Additional Documentation Requests (ADRs) – documentation was not submitted to Novitas in a timely manner in order to support the services billed to Medicare.
    - **Billing Errors** – Upon receipt of the additional development request, the provider deemed the service was billed in error to Medicare.

NOVITAS TARGETED PROBE AND EDUCATE (TPE) REVIEW

Drugs and biologicals

- Drug injections (HCPCS J2778, J2505, J0897, J0178, **J1745**, J9355)
- Top denial/partial denial reasons:
  - The most common reasons for denial or partial denials are the following:
    - **Scope of practice** – The service was performed by a nurse practitioner that was outside of the practitioner's scope of practice to be performing the drug injection.
    - **Medical necessity of services** – Documentation submitted for review did not support the service as medically reasonable and necessary.
      - Documentation did not support the medical necessity of the dosage administered.
      - Documentation did not support the medical necessity of the drug administered.
    - **Insufficient documentation** – Insufficient documentation was provided to support the services as billed to Medicare. Novitas Medical Review makes multiple attempts to correct these error types before completion of the review. Below are the following denial reasons for insufficient documentation that we were not able to resolve:
    - **Incorrect date of service** – Documentation did not support the date of service billed on the claim.
    - **No response to Additional Documentation Requests (ADRs)** – Documentation was not submitted to Novitas in a timely manner in order to support the services billed to Medicare.

COLLECTING FOR INFUSION SERVICES

BASS BERRY SIMS

BENEFICIARY INDUCEMENT CIVIL MONETARY PENALTY
42 U.S.C. §1320a-7a(a)(5)

Cannot offer or transfer remuneration to federal health care program beneficiaries that is likely to induce beneficiaries to order or receive an item or services from a particular provider, practitioner or supplier

"Civil Statute—applies to providers, practitioners and suppliers

Remunerations includes waivers of copayments and deductible amounts (or any part thereof) and transfers of items or services for free or less than fair market value

Some exclusions, e.g., gifts of nominal value

Civil Penalties: $21,113-22,427 for each act

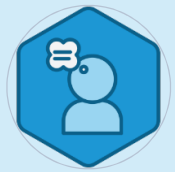
Treble (3x) damages

Exclusion from Federal health care programs

ANTI-KICKBACK STATUTE ("AKS")
42 U.S.C. §1320a-7b(b)

Cannot request or accept anything of value in exchange for referrals, purchases, or orders of items or services directly or indirectly reimbursed by federal health care programs

- "Anything of Value" is broad:
  - Gifts
  - Meals
  - Grants
  - Fees
  - Value-Added Services
  - Free Samples



- No intent to violate or knowledge of the statute is required
- A violation can be found even if there is only one purpose to induce referrals among other legitimate reasons for the remuneration
- There does not have to be an impact on reimbursement

- Criminal or Civil Penalties: $105,563 – 112,131 per offense
- If it's a "knowing" violation, then CMP liability can result
- If reimbursement was involved, then FCA penalties may also apply
- Exclusion from federal health care programs

PATIENT COLLECTIONS CONSIDERATIONS

- Coordination of benefits (i.e., primary vs. secondary insurance)
- Patient discount programs and savings cards
- Robust financial responsibility policies and communication with patients around amounts due
- Co-pay/deductible amount collected at time-of-service, as appropriate
- Payment plan parameters (i.e., minimum payment amount and maximum term)
- Well-documented and annually refreshed financial hardship policy and qualification process
- Demonstrated and documented attempts to collect patient-responsible amounts including patient statements, notes on verbal contact, etc.
- Formalized write-off policy and approval process

COORDINATION OF BENEFITS

- Emphasis on patient registration/intake functions and need for accurate demographic and insurance information
- Regular inquiries related to insurance information and eligibility verification
- Insurance follow-up processes that allow for identification of rejected/still outstanding claims
- Monitoring for accuracy in claim transfer from primary to secondary and resulting patient-responsible amount, if applicable

PATIENT DISCOUNT PROGRAMS AND SAVINGS CARDS

Enrollment and patient registration

Eligibility criteria
(i.e., exclusion of Medicare beneficiaries)

ROBUST FINANCIAL RESPONSIBILITY POLICIES

- Requirement for patients to document acknowledgment of financial responsibility policy including payment terms, cancellation policy, etc.
- Importance of communicating amount due to patient prior to time-of-service, especially with high-cost drugs

CO-PAY / DEDUCTIBLE COLLECTION

- Likelihood of collection is much higher when obtained at time-of-service vs.
  post-service.
- Include language in financial responsibility policies that emphasizes payment expectations.
- If patient cannot pay in full, create policy / threshold for partial payment.
  - For example, no less than 50% due at time-of-service with card on file for remainder at
    pre-determined time.

PAYMENT PLAN PARAMETERS

- Focus on standardization of parameters vs. evaluation on case-by-case basis.
- Consider setting minimum monthly payment amounts based on overall balance.
- Determine term limits (e.g., 6 months, one year, etc.).
- Explore mechanisms for card storage and automatic withdrawal vs. manual processing.

RELEVANT LAW: CMP COPAY WAIVER EXCEPTION

- The term "remuneration" includes the waiver of coinsurance and deductible amounts (or any part thereof), and transfers of items or services for free or for other than fair market value. The term "remuneration" does not include—(A)the waiver of coinsurance and deductible amounts by a person, if—(i)the waiver is not offered as part of any advertisement or solicitation;
- (ii)the person does not routinely waive coinsurance or deductible amounts; and
- (iii)the person—(I)waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need; or
- (II)fails to collect coinsurance or deductible amounts after making reasonable collection efforts
- 42 USC 1320a-7a(6)(A)

RELEVANT LAW: AKS COPAY WAIVER SAFE HARBOR

- Waiver of beneficiary copayment, coinsurance and deductible amounts. As used in section 1128B of the Act, “remuneration” does not include any reduction or waiver of a Federal health care program beneficiary's obligation to pay copayment, coinsurance or deductible (for purposes of this subparagraph (k) “cost-sharing”) amounts as long as all the standards are met within one of the following categories of health care providers or suppliers.
- (1) If the cost-sharing amounts are owed to a hospital for inpatient hospital services for which a Federal health care program pays under the prospective payment system, the hospital must comply with all of the following three standards:
- (i) The hospital must not later claim the amount reduced or waived as a bad debt for payment purposes under a Federal health care program or otherwise shift the burden of the reduction or waiver onto a Federal health care program, other payers, or individuals.
- (ii) The hospital must offer to reduce or waive the cost-sharing amounts without regard to the reason for admission, the length of stay of the beneficiary, or the diagnostic related group for which the claim for reimbursement is filed.
- (iii) The hospital's offer to reduce or waive the cost-sharing amounts must not be made as part of a price reduction agreement between a hospital and a third-party payer (including a health plan as defined in paragraph (l)(2) of this section), unless the agreement is part of a contract for the furnishing of items or services to a beneficiary of a Medicare supplemental policy issued under the terms of section 1882(t)(1) of the Act.
- (2) If the cost-sharing amounts are owed by an individual who qualifies for subsidized services under a provision of the Public Health Services Act or under Titles V or XIX of the Act to a federally qualified health care center or other health care facility under any Public Health Services Act grant program or under Title V of the Act, the health care center or facility may reduce or waive the cost-sharing amounts for items or services for which payment may be made in whole or in part by a Federal health care program.

RELEVANT LAW: AKS COPAY WAIVER SAFE HARBOR

- (3) If the cost-sharing amounts are owed to a pharmacy (including, but not limited to, pharmacies of the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations) for cost-sharing imposed under a Federal health care program, the pharmacy may reduce or waive the cost-sharing amounts if:
- (i) The waiver or reduction is not offered as part of an advertisement or solicitation; and
- (ii) Except for waivers or reductions offered to subsidy-eligible individuals (as defined in section 1860D-14(a)(3)) to which only requirement in paragraph (k)(3)(i) of this section applies:
- (A) The pharmacy does not routinely waive or reduce cost-sharing amounts; and
- (B) The pharmacy waives the cost-sharing amounts only after determining in good faith that the individual is in financial need or after failing to collect the cost-sharing amounts after making reasonable collection efforts.
- (4) If the cost-sharing amounts are owed to an ambulance provider or supplier for emergency ambulance services for which a Federal health care program pays under a fee-for-service payment system and all the following conditions are met:
- (i) The ambulance provider or supplier is owned and operated by a State, a political subdivision of a State, or a tribal health care program, as that term is defined in section 4 of the Indian Health Care Improvement Act;
- (ii) The ambulance provider or supplier engaged in an emergency response, as defined in 42 CFR 414.605;
- (iii) The ambulance provider or supplier offers the reduction or waiver on a uniform basis to all of its residents or (if applicable) tribal members, or to all individuals transported; and
- (iv) The ambulance provider or supplier must not later claim the amount reduced or waived as a bad debt for payment purposes under a Federal health care program or otherwise shift the burden of the reduction or waiver onto a Federal health care program, other payers, or individuals.
  - 42 cFR 1001.952(k)

FINANCIAL HARDSHIP AND QUALIFICATION

1. **If offering financial hardship write-offs, ensure qualification process is documented and applied universally to patients.**

2. **Maintain documentation requested.**
(e.g., bank statements, income information, etc.)

3. **Request refreshed documentation at least annually to ensure hardship decision is still pertinent.**

4. **Consider thresholds for discount.**
(e.g., partial vs. full, based on income)

ATTEMPTS TO COLLECT

- Any and all communication with patient (e.g., verbal, written, etc.) should be documented in the patient record.
- Patient statements sent on monthly basis.
- Maintain documentation demonstration of good faith efforts to collect (e.g., at least three patient statements before evaluating for further collections/write-off).

WRITE-OFF POLICY AND APPROVAL

- Ensure patient account includes all documentation related to good faith efforts to collect.
- Implement detailed write-off codes for ease of tracking volume/value associated with write-offs.
- Require managerial or supervisor approval for write-offs over certain amount.
- Review payer contract terms for potential compliance risk.

CASE STUDIES

CASE STUDY #1

- Medical practice diligence review that included a practice operations assessment and coding and documentation review of infusion services
- Remote coding and documentation review, followed by remote interviews of clinical staff at the conclusion of the review
- Significant findings related to infusion services:
  - Inconsistent process for documentation of physician order within the EMR at all practice locations
  - Lack of physician order to support medical necessity of infusion services provided
  - Inappropriate dosage of medication relative to patient weight for chemotherapy / highly-complex drug
  - Lack of drug wastage documentation

CASE STUDY #2

- Medical practice diligence review that included a coding and documentation review of infusion services
- Remote coding and documentation review, followed by additional data analysis and interviews at the conclusion of the review
- Findings related to infusion services:
  - Inappropriate billing of infusion supplies used to facilitate infusion services
    - A4216 *Sterile water, saline and/or dextrose, diluent/flush, 10 ml*
    - A4221 *Supplies for maintenance of non-insulin drug infusion catheter, per week (list drugs separately)*
    - A4223 *Infusion supplies not used with external infusion pump, per cassette or bag (list drugs separately)*
    - E0776 *IV pole*
    - S1015 *IV tubing extension set*
  - Administration of medication and billing of services outsourced to a third-party billing under the practice's NPI
  - No Medicare reimbursement for supplies, but commercial payers were reimbursing the practice
  - Sample review of 20 claims identified an overpayment of ~$2,500

CASE STUDY #3

- Specialty pharmacy and ambulatory infusion suite diligence review that included a compliance program administration review, operational compliance review, infusion coding review, and pharmacy billing review
- Findings related to infusion services:
  - Lack of formal billing and collections policies and procedures that outline the specific parameters and thresholds for payment plans, write-offs, patient statements and follow-up, and other revenue cycle-related items
  - 15 of 46 pharmacy claims reviewed did not have documentation related to payment of the patient-responsible amount or transfer of remaining balance to a secondary insurance or co-pay assistance program; no patient statements related to these encounters either
  - Incomplete infusion services documentation, specifically, infusion start and stop time, IV access location, and drugs infused
  - Inappropriate billing of infusion add-on CPT codes due to insufficient supporting time documentation

KEY TAKE-AWAYS

- Monitor coding and documentation compliance through regular audits to help identify potential risk and opportunities for improvement.
- Maintain easily accessible and auditable records and documentation pertaining to patient co-pay and deductible collection, payment plan parameters and qualification decisions, and associated write-offs.

SPEAKERS

Carine Leslie
RHIA, CCS
Senior Manager, Healthcare Consulting

PYA, P.C.
800.270.9629
cleslie@pyapc.com

Katie Garmon
MSHA, CPhT, CAC
Manager, Healthcare Consulting

PYA, P.C.
800.270.9629
kgarmon@pyapc.com

Shannon Wiley
JD
Member

Bass, Berry & Sims PLC
901.543.5987
swiley@bassberry.com

THANK YOU

BASS
BERRY
SIMS