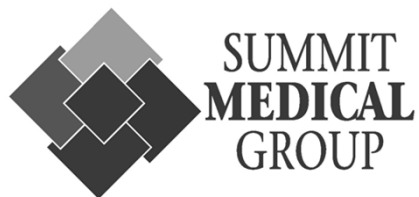







***Research Billing Compliance Program –
From Zero to 100 in 60 seconds!***



Who are we?







Maynard G. Bensley, MD

William H. Lawrence, MD

Since 1919, Summit Medical Group has provided high-quality, patient-centered care. 100 years later our mission remains the same.



Mission

To deliver high-quality, cost effective care through a comprehensive, integrated multi-specialty group of practitioners

Values



Trust, Transparency, Open Communications, Honesty, Compassion, Adaptability, Integrity, Loyalty

Strategic Pillars

Growth

Access,
Service &
Quality

Finance &
Affordability



Summit Medical Group – New Jersey

- One of the largest and oldest multi-specialty physician groups in the country
- Strong presence in heavily insured, densely populated and growing markets in New Jersey
- Comprehensive integrated clinical model across the care continuum with exceptional quality and strong ability to manage total cost of care

\$725M

2018 SMG Revenue

~15%

Revenue Growth

~915

Providers

~125

New Providers in 2018

~2.3M

2018 Patient Visits

550,000

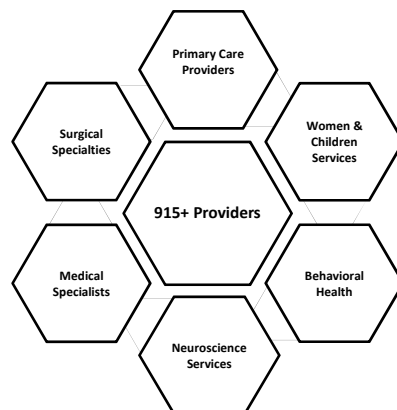
2018 Unique Patients

95%

Patient Satisfaction

80+

Locations



- Acupuncture
- Advanced Interventional Endoscopy
- Allergy and Immunology
- Ambulatory Surgery
- Anesthesiology
- Audiology
- Behavioral Health and Cognitive Therapy
- Breast Care and Surgery
- Cancer Care
- Cardiology
- Cardiopulmonary Center
- Chiropractic Medicine
- Clinical Pharmacy
- Clinical Research
- Colon and Rectal Surgery
- Dermatology
- Diabetes and Endocrinology
- Ear, Nose and Throat
- Extensivist Medicine
- Family Medicine and Primary Care
- Gastroenterology
- General Surgery
- Genetic Counseling
- Geriatric Services
- Gynecologic Oncology
- Hand Surgery
- Head and Neck Surgery
- Hospitalist Medicine
- Infectious Disease
- Infusion Center
- Internal Medicine
- Interventional Radiology
- Laboratory Medicine and Pathology
- Massage Therapy
- Nephrology
- Neurology
- Neurosurgery
- Nutrition Services
- Obstetrics and Gynecology
- Occupational Therapy
- Ophthalmology
- Orthopedics and Sports Medicine
- Pain Management
- Patient Relations
- Pediatric Care
- Physical Medicine and Rehabilitation
- Physical Therapy
- Plastic and Reconstructive Surgery
- Podiatry
- Pulmonology
- Radiation Oncology
- Radiology and Imaging
- Rheumatology
- Sleep Disorders Center
- Social Work and Care Management
- Speech Therapy
- Surgical Oncology
- Urgent Care Center
- Urology
- Vascular Medicine and Surgery
- Women's Multispecialty Health Center



ASCs - Florham Park - 10 ORs, Berkeley Heights - 6 ORs



SMG patients have reported a 95% rate of satisfaction with all aspects of their ambulatory surgery care

23,750 Cases in 2018

- Breast biopsies
- Colonoscopies
- Ear, nose, and throat surgeries
- Endoscopies
- Minimally invasive GI procedures
- Laparoscopic orthopedic treatments
- Foot (podiatric) surgeries
- Hernia repairs
- Orthopedic surgeries
- Pain management
- Plastic surgeries and cosmetic surgeries
- Sports medicine surgeries
- Vein ligation
- Urologic surgeries
- 24-hour joints and bariatric sleeve in planning



Imaging Services

- MRI
- PET CT
- Nuclear Medicine
- X-ray Fluoroscopy
- Mammography
- Breast Ultrasound
- Linear Accelerator



Laboratory & Pathology

- SMG Lab processed over **5 Million Results** in 2018
- **350,000+** venipunctures at SMG sites
- Pathology processed over **120,000** pathology slides
 - Dermatology
 - Obstetrics and Gynecology
 - Podiatry
 - Gastroenterology
 - Surgical cases (e.g., breast, thyroid, liver)



4 High Acuity Urgent Care Centers



Monday-Friday 8:00am - 8:00pm
Saturday and Sunday 8:00am - 5:00pm

We're Here To Help

92,798 Visits in 2018



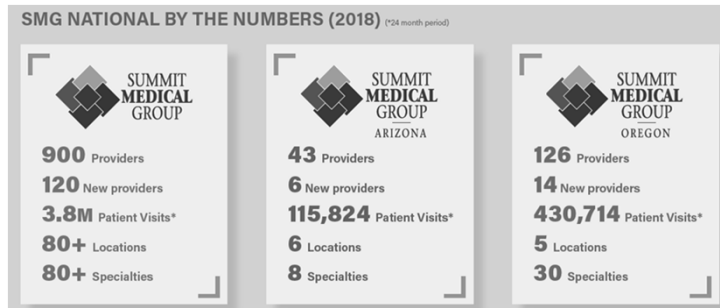
Integrated Oncology Services

- New state-of-the-art 130,000 square foot ambulatory cancer center in Florham Park, New Jersey
- Fully integrated, multidisciplinary cancer care program
- Access to the most advanced cancer treatments and support services:
 - World-class interventional radiology
 - Radiation oncology suite with cutting-edge linear accelerators in two primary locations
 - Chemotherapy infusion suites in multiple locations
 - Comprehensive breast care center with state-of-the-art imaging in two locations
- 60 providers and 240 support staff



Summit Health Management

- Founded in 2014
- Management services for Summit Medical Group in New Jersey and mid- to large-sized physician practices across the United States.



Who are you?

- How many Clinical Research Coordinators in audience?
- How many from private physician practices?
- How many with a formal clinical trial billing compliance program?
- How many regularly meet with the Corporate Compliance team and others? (CRC, Investigators, revenue cycle, coders)?
- How many of those in the audience have coders within clinical research teams?



Clinical Research at the Summit Medical Group

- **Historically: two CRCs; 12 investigators, one location; no more than 8 protocols at any given time.**
- **Today: 7 staff: 6 CRCs, 1 regulatory admin; 42 investigators, 3 locations; lots more protocols!**



Research Billing Compliance!

- **Why, Where, Who and What?**



Why?

Consequences of non-compliant research billing include risks of inappropriately billing for services that:

- May have already been paid for by a Sponsor (double billing)
- Were promised for free in an ICF
- Are for research purposes only
- Are part of a non-qualifying clinical trial
- Many other consequences to consider as well!



Where do we start?

- Statutes/regulations
- Governmental guidance
- CTP
- Contracts
- Informed Consent language
- Identifying key players within organization and roles.

Keeping in mind that the Summit Medical Group is a private physician practice - -not a hospital, university, etc.



Statutes/Regulations/Government Guidance

- CMS Clinical Trial Policy, July 2007
 - Local Coverage Decisions
- CMS Clarification, September 2008
- FDA Categorization of Investigator Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions: Guidance for Sponsors, Clinical Investigators, Industry, Institutional Review Boards and Food and Drug Administration Staff





- Healthcare fraud is a top enforcement priority of government agencies
- Federal government has recovered billion from healthcare fraud enforcement
- FCA establishes liability for anyone who submits a false claim for payment to the government - specific intent not required
- Federal penalties for violating the FCA are severe and include fines up to 3x the amount of each claim, plus additional penalties AND possible exclusion from federal health care programs
- Obligation to respond promptly when there is a reason to suspect potential overpayment (potential liability for reverse false claim)



Anti-Kickback Statute

- Anti-Kickback – potential liability:
 - Sponsor payments to researcher at or above fair market value
 - “Sham” research studies
 - Gifts, entertainment, and/or other incentives provided by industry sponsors
 - PI selection criteria – failure to identify and/or follow bona fide investigator selection criteria
 - Conflicts of interest – failure to disclose



False Claims Act

- Civil statute that makes it unlawful (in relevant part):
 - To knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval by the government
 - To knowingly make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim
- Applies to “all” responsible persons:
 - Sponsors
 - Institutions
 - Investigators
 - Employees and agents



False Claims Act (cont'd)

- Knowledge requirement, defined as:
 - Actual knowledge,
 - Deliberate ignorance of the truth or falsity of the information,
 - Reckless disregard of the truth or falsity of the information
- No specific intent to defraud required under the statute



False Claims Act – Possible Liability in Research Study

- Double-billing or billing Medicare for experimental services
- Mischarging of costs to grants and award projects:
 - False time and effort reporting (e.g., charges of persons not eligible to work on the project or billing for services not rendered)
 - Inflating grant research costs
 - Inadequate accounting policies
 - Failure to refund unused grant proceeds
 - Improper cost-sharing – direct vs. indirect costs
 - Billing for non-reimbursable items or services (e.g., items provided free by manufacturer or sponsor)



False Claims Act – Possible Liability in Research Study

- False certifications and assurances (express certifications to secure funding)
 - Principal Investigator's representations regarding expertise and work to be performed on the study
 - Results or adverse events
 - Compliance with a regulation or requirement that is material to conducting the trial, research, or other funded activity



Who do we start with?

- Revenue Cycle – Biller/Pre-authorization specialist
- Finance
- Clinical Research Coordinators
- Investigators
- Coding and Compliance
- Corporate Compliance
- Legal

Task Force!



Task Force:

- Began to meet bimonthly to identify action items, review contract terms, guidelines and regulations.
- A review of payor policies on clinical trial billing was conducted.
- A shared drive created with “alert” capabilities to store protocols, payment terms, NCD and blank informed consent by NCT number so that entire team may have access.
- SOP for Clinical Trial Billing Compliance created.
- Education of all investigators, clinical research staff, pre-authorization specialist and coders.



Contracts, Exhibits and Schedules – Oh My!

- What does the contract have to do with it?
- A LOT!
- Contracts are broken down into 3 main sections:
 - 1) Main body of the contract that identifies compensation/financial terms
 - 2) Exhibit incorporating the protocol
 - 3) Compensation arrangement/Sponsor Budget - -usually in the form of an Exhibit

Oftentimes, we also see Letters of Indemnity directly from the Sponsor when a CRO is involved.



Contracts, Exhibits and Schedules – Oh My!

- Contractual obligations that oftentimes stem from legal obligations:
 - 1) No double billing!
 - 2) Institution and/or Investigator shall not bill any third party for any Study Drug or other items or services furnished by the Sponsor through CRO in connection with the Study, or any services provided to subjects in connection with the Study for which payment is made as part of the Study, except as may be specifically authorized by the Exhibit...



Framework

- Common framework for Clinical Research Billing
 - Does the clinical research study qualify for coverage?
 - Which items and services required by the research study meet the definition of “routine costs”?
 - Does the third-party’s reimbursement rules allow for coverage of the specific routine costs?



Step 1: Does the clinical research study qualify for coverage?

- NCD to be performed upon contract/payment terms from sponsor
- Internal Policy defines this “Coverage Analysis” as the identification and classification of each item, procedure and service associated with a Clinical Trial to determine those charges appropriately billed to Medicare or other Third-Party Payor in accordance with the Clinical Trial Policy.



Step 2: Which items and services required by the research study meet the definition of “routine costs”?

Review of protocol, contract, informed consent form

Protocol number	NCT Number		MCA Billing Grid				R= Research, Sponsor Pays					
Sponsor						S=SOC/Routine costs, Patient or Insurance Pays						
						N=No Funding, not covered by sponsor or insurance						
Coverage Analysis		Protocol Schedule of Events										
			Cycle 1				Cycle 2+	EOT	EOT +30d	q9w FU (Disease Status)	q12w (Survival)	
Procedure	Pre-Screen	Screening	C1D1	C1D8	C1D15	C2D1						
ICF	R											
Eye Exam		*				*	*					
Eligibility	R	R										
Con-meds/prior Tx	R	R	R	R	R	R	R	R				
Demographic/Med Hx		R										
PE, wt, ht		S	S	S	S	S	S	S				
VS		S	S	S	S	S	S	S				
12 lead ECG		*	*		*	*	*	*				
ECOG		S	S	S	S	S	S	S				
CT or MRI		S**				S**			S**			
QOLs		R				R	R					
Review AE		S	S	S	S	S	S	S				
Central Lab		S	S	S	S	S						
Genomic testing		R										



Step 3: Does the third-party's reimbursement rules allow for coverage of the specific routine costs?

- To be completed at time subject signs informed consent



Workflow for Patient Enrollment

- Step 1 – Identifying the patient as the Study patient.
 - Assure the patient is identified in the EMR with sponsor name, protocol, NCT number
- Step 2 – Review patient insurance/coverage.
 - Notice with patient information, NCT number, NCD form sent to pre-auth specialist
- Step 3 – Patient alert lets Rev Cycle know not to submit any charges until review of pending charges against budget grid by research manager
- Step 4 – Task Force sub-committee meets and reviews each claim billed to insurance.
- Step 5—quarterly audit/review completed by task force to ensure proper third party billing



Top 5 Questions asked by Patients/Subjects

- Who is going to pay for the study and other medications that I need?
- If a specific diagnostic test is necessary, such as serial CT, who will cover the cost?
- Am I responsible for co-payments if I participate in the trial?
- What do I do if I receive a bill for study services?
- Will my insurance deny coverage if I sign up?



Informed Consent Samples

- **What are the costs of taking part in this study?**

- "Study drug and study procedures will be provided at no cost to you."
- "You or your insurance company will be responsible for paying for procedures, tests and possibly medications that are standard treatment for study participants with breast cancer. Some examples of standard procedures include routine laboratory blood tests, x-rays, MRIs, scans, surgeries, blood transfusions, physicians' charges and routine medical care. Examples of other medications you could possibly require in addition to the study medications include antibiotics or other medications to manage side effects of treatment. Your insurance company may not pay for costs associated with research studies like this one. You are responsible for any charges your insurance company does not pay."
- You may have to pay for some expenses related to this study.
- You will not be paid for being in this study.
- You may be reimbursed for transportation, parking and meal expenses per study visit, related to your taking part in this study. If you do not finish the study, you will be reimbursed for the part of the study that you did complete. However, your expenses could be more than the amount you are reimbursed.



Informed Consent samples

- **Will it cost you anything to be in this study?**

- There are no costs to you for participating in this study. The study drug will be made available to you at no charge and you will not pay for any study-related tests and procedures during your participation in the study. You and/or your insurance provider may be billed for any standard medical care that is not part of this research study.

- **What is being performed specifically for the study?**

- The following tests/procedures are being performed for the purposes of this study, and may not be considered standard care:
 - Urine Pregnancy Tests (for females capable of having children) • Urine drug screen • Eye exams • Recording of symptoms in the electronic diary • Completion of questionnaires • CT scans



SOP

This policy describes the review and coverage determination process for all clinical research-related services, items and procedures at Summit Medical Group, P.A. to ensure appropriate billing compliance with all applicable laws, regulations and contractual obligations.



Any questions? Please reach out to us at kritter@smgnj.com or isenthil@shm.net.

