Commercial Reasonableness Toolkit

ECG MANAGEMENT CONSULTANTS

A Siemens Healthineers Company

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Background

The Stark and anti-kickback laws require physician contracts to meet the standards of commercial reasonableness and fair market value. Until recently, regulatory agencies provided no formal definition for commercial reasonableness; however, in early 2021, CMS and the OIG issued extensive revisions to safe harbors to the federal anti-kickback statutes to clarify valuation requirements that appear in many of the Stark law exceptions.[1] A new definition of commercial reasonableness was provided with the stated intent to reduce compliance burdens on providers and law enforcement, including limiting the need for external consultants to verify compliance. We advise initiating any contract review with an assessment of commercial reasonableness in conjunction with an assessment of fair market value.

The new definition states:

> **Commercially reasonable** means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty.[2]

Commentary on the final rule further states:

> The determination that an arrangement is commercially reasonable does not turn on whether the arrangement is profitable; compensation arrangements that do not result in profit for one or more of the parties may nonetheless be commercially reasonable. We acknowledge that, even knowing in advance that an arrangement may result in losses to one or more parties, it may be reasonable, if not necessary, to nevertheless enter into the arrangement. **Examples of reasons why parties would enter into such transactions include community needs, timely access to health care services, fulfillment of licensure or regulatory obligations, including those under the Emergency Medical Treatment and Labor Act (EMTALA), the provision of charity care, and the improvement of quality and health outcomes**.

In the preamble to the new regulations, CMS stated that the final regulations are "consistent" with its prior positions on phase one of the Stark law issuance, hence the new rules are considered by CMS to be "clarifications" not revisions.

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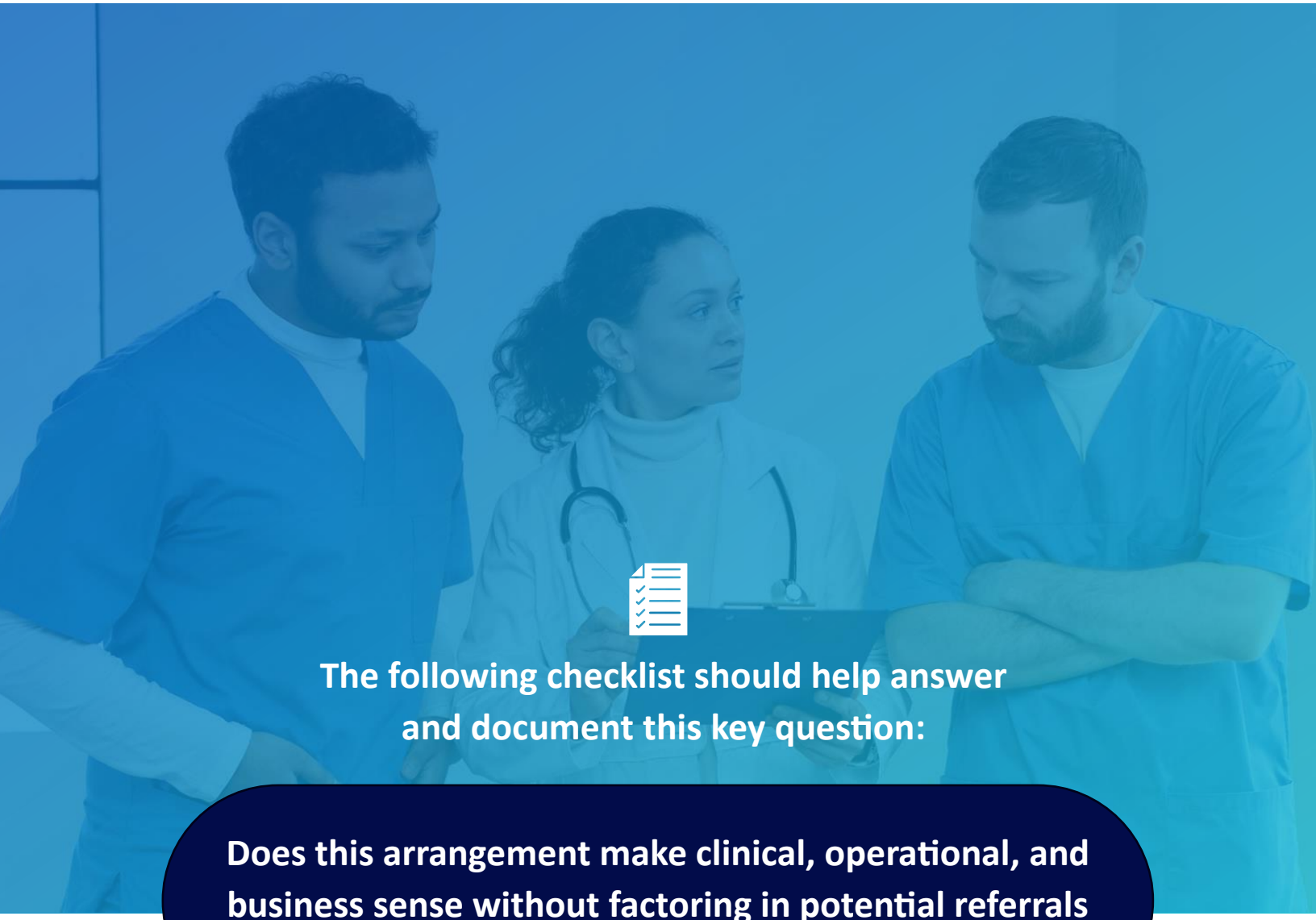
1 https://www.federalregister.gov/documents/2020/12/02/2020-26072/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the.

2 https://www.law.cornell.edu/cfr/text/42/411.351.

In addition to being commercially reasonable, hospital-physician agreements must be consistent with fair market value to comply with federal and state regulations. These are separate legal standards, thus a contract may be consistent with fair market value but not meet the standards of commercial reasonableness in some arrangements.



The following checklist should help answer and document this key question:

Does this arrangement make clinical, operational, and business sense without factoring in potential referrals from the contracting physician?

Commercial Reasonableness Checklist

	Category	Criteria	Impact
	1. **Alignment with Mission and Goals**	Does the arrangement align with and facilitate achievement of the organizational mission and goals?	If not, it may not be commercially reasonable.
	2. **Industry Practice**	Is the arrangement reasonably prevalent in similar organizations (size, type), or are there legitimate reasons for an atypical arrangement?	The more uncommon the arrangement, the less likely it is to be commercially reasonable.
	3. **Frequency and Intensity of Need**	How often is the service needed? How intense is the workload?	If frequency or intensity of service is low, commercial reasonableness may be questionable.
	4. **Alternatives**	Are there less costly alternatives that are equivalent to or better with respect to quality of care?	If yes, the arrangement may not be commercially reasonable.
	5. **Duplication**	Is there a duplication of service arrangements?	If yes, the arrangement may not be commercially reasonable.
	6. **Financial Performance**	Does the cost of the arrangement justify identifiable benefits?	If the associated service results in or contributes to economic losses, it may not be commercially reasonable unless there is a demonstration of need or other justification.
	7. **Qualifications**	Is the physician qualified to provide the services?	If not, the arrangement may not be commercially reasonable.
	8. **Evaluation Metrics**	Are there well-defined and objective measures of performance? Is the evaluation process defined?	If not, the arrangement may not be commercially reasonable.
	9. **Payment Terms**	Is there a defined payment amount, with a defined maximum payout?	If not, the arrangement may not be commercially reasonable.

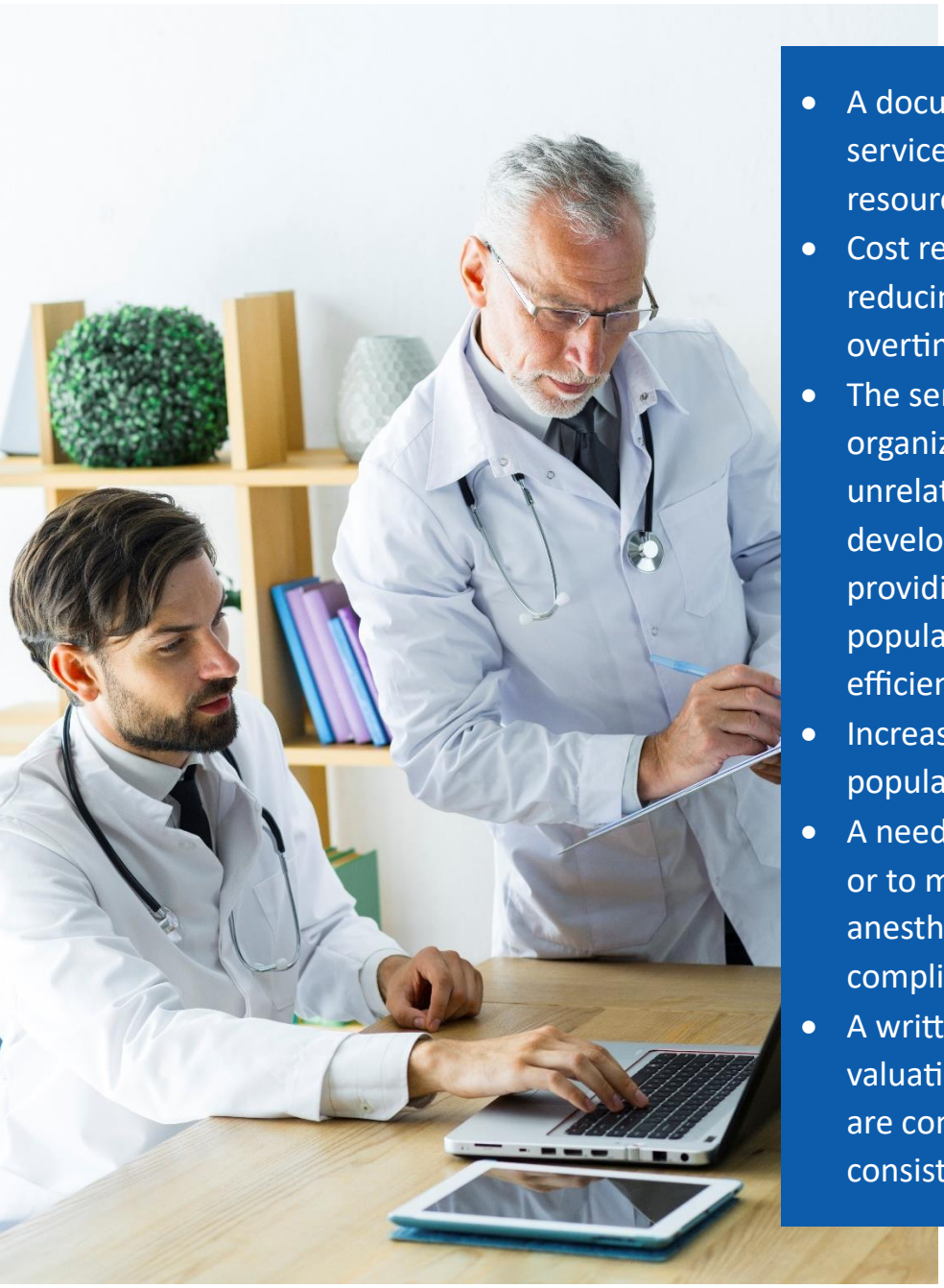
High-Risk Circumstances Checklist

In addition to the checklist provided above, the following situations should be reviewed and documented carefully with respect to necessity and commercial reasonableness since they represent areas of prior Stark law violations:

- Call coverage services with very low frequency demand for emergency department services (e.g. dermatology)
- Call coverage by two specialties with overlapping scope of practice
- Coverage arrangements for multiple campuses that are in close proximity, particularly for low-volume emergency departments
- Directorships for programs with only one physician or a small single-specialty group of physicians providing the service
- Multiple directorships for the same specialty
- Multiple directorships with the same physician
- Multiple agreements (coverage or medical administrative) with the same medical group
- Communications or agreements that indicate the value of referrals resulting from the arrangement
- Agreements with employed physicians that, when combined with paid salary, exceed fair market value benchmarks (since total compensation benchmarks include compensation from all sources, including administrative and call services)
- Unique arrangements with a subset of physicians providing the same service

Examples of Nonstandard Justifications

CMS and the OIG have indicated that there are circumstances that could be commercially reasonable even when an arrangement does not meet standard criteria. In these situations, the agreements and circumstances should be reviewed and justification of commercial reasonableness carefully documented. Circumstances cited as possible valid reasons to pay for services not typically considered reasonable include:



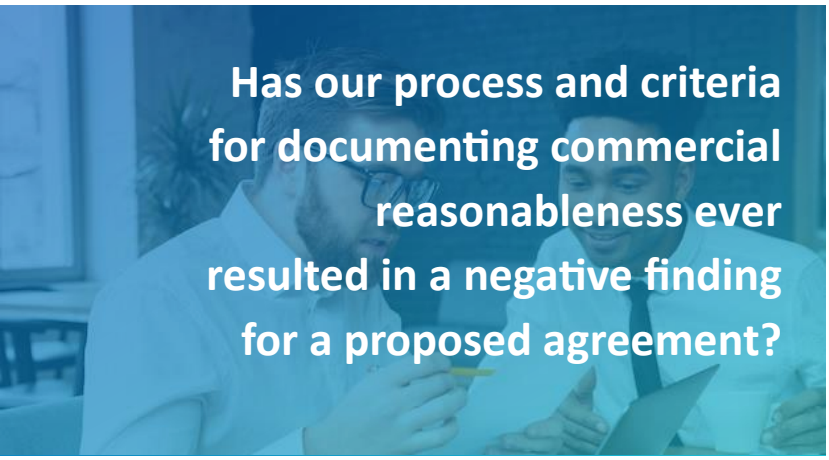
- A documented community need for the service or insufficient local/regional resources to address community need.
- Cost reduction, such as reducing/eliminating use of locums or overtime.
- The service supports achievement of the organizational mission or goals that are unrelated to referrals, such as development of new services or programs, providing services to underserved populations, and addressing quality or efficiency initiatives.
- Increasing access to underserved populations.
- A need to meet regulatory requirements or to maintain basic services, such as anesthesia coverage or EMTALA compliance.
- A written opinion by a professional valuation expert that the circumstances are commercially reasonable and consistent with fair market value.

Assessing Commercial Reasonableness

The determination of commercial reasonableness can be more subjective than determining fair market value. It is not enough to simply assert that an agreement (1) is necessary for the operation of the hospital, (2) makes business sense, and (3) has a compensation level that was established without regard for potential referrals.

Documentation of the benefits and need for the specific contract for the specific situation, in addition to market data supporting the prevalence of the type of contract, will bolster compliance reviews. Evaluating commercial reasonableness should be the first step in any compliant contract review process. Using a checklist like the one in this document provides a framework for documentation of your organization's consideration of commercial reasonableness.

Be cautious if your institution has never had a contract that failed the "test" of commercial reasonableness. A prudent question to ask yourself, the valuation consultant, contracting director, or facility administrator is:



If the answer to this question is "no," the process and criteria for the judgment being applied may be ineffective in the absence of a thoughtful, consistent commercial reasonableness review and documentation process.

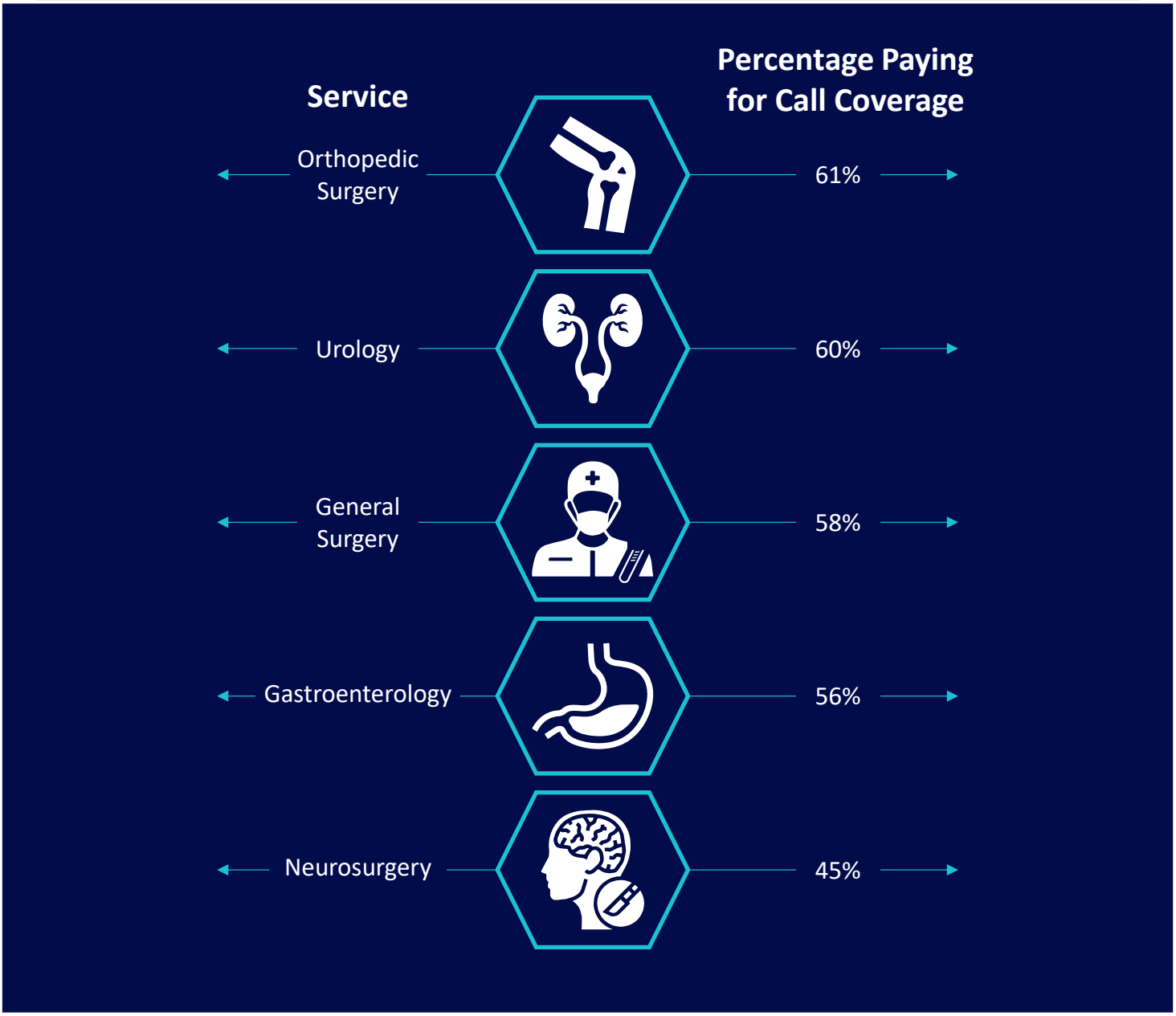
With the right tools, policy, and education, documenting commercial reasonableness should become a routine and straightforward process for most transactions. This resource can help to identify contracts that need additional documentation or external validation to meet the standard of commercial reasonableness.

MD Ranger® Percentage Paying and Number of Positions of Benchmarks

Some types of market data can help to document commercial reasonableness. Because MD Ranger collects subscriber data that includes a comprehensive inventory of all contracted physician services, it can report the percentage of hospitals in its database that pay separately for the service. Note that we are unable to break out call coverage payments that are embedded into the base salary.

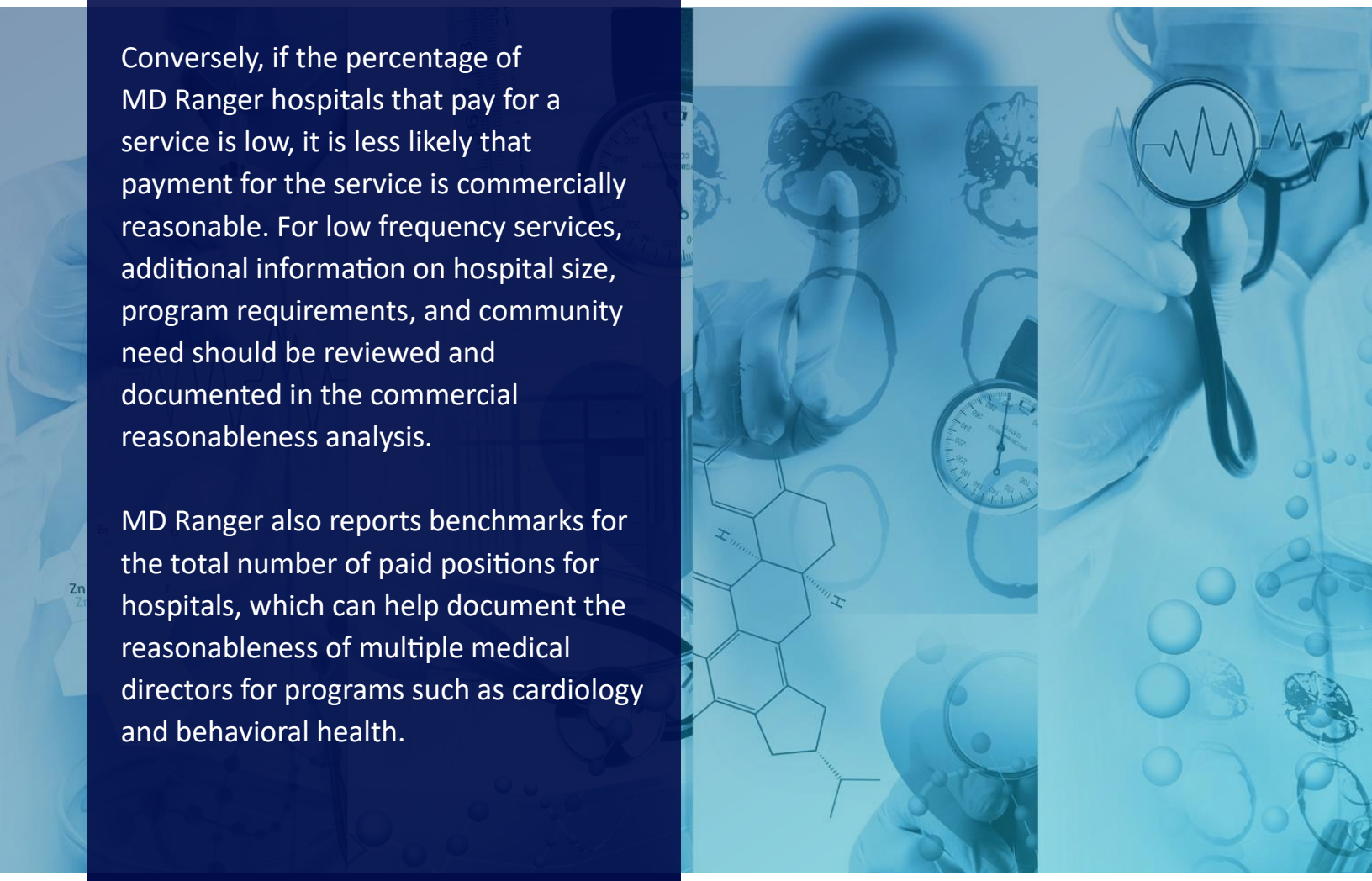
If the percentage of MD Ranger hospitals that pay for a service is high, it is a strong indication that paying for the service is commercially reasonable. The percentage benchmarks apply to all hospitals and do not take into account hospital characteristics such as hospital size, trauma status, physician supply, or factors that could influence a commercial reasonableness assessment, although special reports can be ordered to test particular characteristics.

Top-Five Most Frequently Paid Coverage Services



Conversely, if the percentage of MD Ranger hospitals that pay for a service is low, it is less likely that payment for the service is commercially reasonable. For low frequency services, additional information on hospital size, program requirements, and community need should be reviewed and documented in the commercial reasonableness analysis.

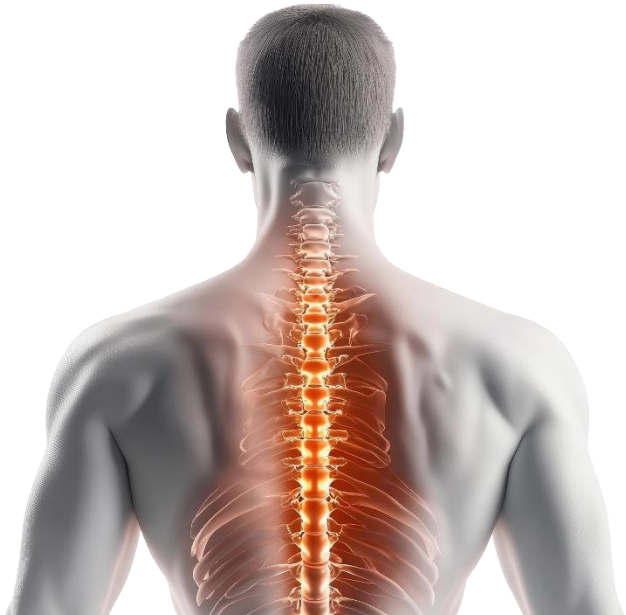
MD Ranger also reports benchmarks for the total number of paid positions for hospitals, which can help document the reasonableness of multiple medical directors for programs such as cardiology and behavioral health.



Case Studies

Spine Surgery Call Coverage

A busy Level II Trauma Center maintained neurosurgery coverage through a contract with a panel of neurosurgeons, all of whom had full privileges that included spine surgery. The contract required the on-call physician to be restricted for the full 24-hour day, precluding them from performing nonemergency surgery. Furthermore, the neurosurgery contract provided first and second call, as required for trauma certification. A panel of orthopedic surgeons that specialize in spine surgery proposed that the hospital create an on-call panel for spine cases. Because the hospital had already secured continuous and restricted coverage for emergency spine injuries from qualified surgeons, and because spine surgery is rarely needed on an emergent basis, the proposed additional coverage arrangement was found to be duplicative and, therefore, did not meet the standard of commercial reasonableness.



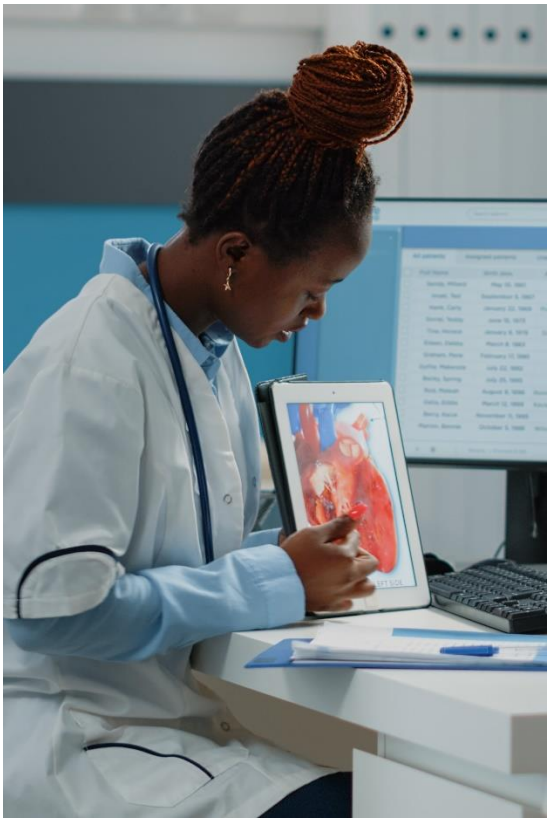
Case Studies

Electrophysiology (EPS) Cardiology Medical Director and Comanagement Agreement

There was a single EPS specialist on the staff of a community hospital. The hospital proposed to contract with this physician to be the medical director of EPS with responsibilities for outreach to other hospitals, clinical quality improvement, and a comanagement agreement that focused on quality and cost control.

By applying the review criteria in the commercial reasonableness checklist, it was found that one segment of the position, the comanagement agreement, was commercially reasonable. The work was directly supportive of the hospital's goals for quality improvement and cost management, and the agreement included defined time commitments, measurable performance outcomes, and a defined level of compensation that was found consistent with fair market value.

However, the segments of the work for outreach to other hospitals and clinical quality improvement were found not to be commercially reasonable. As the sole EPS physician on the medical staff, the physician's private practice was indistinguishable from the medical staff in the EPS subspecialty, hence the hospital should not be paying this physician for marketing and internal quality reviews of his private practice. Further, there was no practical way to evaluate how any work done exclusively for the hospital might be different from the physician's private practice work.



Case Studies

ICU Coverage of Two Campuses

A two-hospital system had campuses 15 minutes apart. The hospital had two separate agreements with a single group of pulmonary medicine/critical care physicians. Each agreement provided for a combination of on-site coverage (consistent with Leapfrog standards) at each campus during daytime hours and on-call coverage for other hours of the day. The agreements called for separate physicians for each hospital.

The volume of off-hours calls was relatively low, with a very low probability of simultaneous calls from each campus. This low volume raised a significant concern about whether it was commercially reasonable to pay separate physicians in the same medical group to be on-call at each hospital. The hospital needed to consider if there was a reasonable alternative to distinct agreements: specifically, could there be a single agreement for the group to cover each campus during the daytime hours and to provide a combined call panel for after-hours coverage? Relevant factors to review were ICU census, frequency of call, patient profiles for each ICU, etc.

Case Studies

Rural Hospital Specialty Services

A 30-bed hospital in a town two hours from the closest large hospital maintained a basic emergency department, medical, and surgical services. Although it did not provide pediatric services, a regional children's hospital had held monthly specialty clinics in cardiology and neurology. The children's hospital determined that it was no longer viable to provide monthly on-site services at no cost and requested payment for providing phone consultations with transfer assistance as well as stipend support for quarterly on-site visits.

Coverage payments and clinic stipends for many pediatric specialties are uncommon, particularly at small and rural hospitals; however, large children's hospitals often have outreach clinics to enhance access to underserved populations. The hospitals reviewed outreach clinic visits, hospital emergency visits, and patients' residence and determined that the monthly visits were underused, but quarterly visits would be fully subscribed. Furthermore, the families requiring the service could not easily travel to the regional hospital for care management. The children's hospital provided evidence that there was a shortage of physicians in the specialty and, in order to recruit additional physicians to provide the outreach services, a subsidy was needed, given the time and cost of travel and poor payer mix. The rural hospital was able to negotiate a monthly phone coverage payment for emergency and transfer support and a daily stipend for the quarterly on-site clinic days. Payment was based on an analysis of collections data, on-site and travel time and compensation, and benefit and practice support costs for the specialists.

The arrangement was determined to be commercially reasonable based on documented community need and the estimated cost of providing the services.

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Standardize and streamline the FMV process with MD Ranger.

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- **Compare physician costs, contracts, salaries, and productivity** to similar organizations, and analyze spending across your health system or medical group.
- **Rely on MD Ranger's large database and sample sizes** to provide stable benchmarks.
- **Evaluate commercial reasonableness** using statistics that capture the percentage of hospitals paying for a service.

AVAILABLE BENCHMARKS

Call coverage per diems, per activation, per episode

Medical director hourly rates, annual hours, annual rates

Physician administrative and leadership roles like quality, care/case management, chief of staff, and more

Hospital-based physician stipends and other payments, including incentive components

Clinical hourly rates

Diagnostic testing

Telemedicine arrangements

Locum tenens rates

Match your organization to available benchmark slices:

Trauma status

Bed size

Average daily census

Teaching status

Urban vs. rural location

Payer mix

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