

## UW HEALTH JOB DESCRIPTION

### Manager, Regulatory/Quality Systems

Job Code: 850009	FLSA Status: Exempt	Mgt. Approval: M. Roberts/C Braly	Date: April 2023
Department: 3036001 Organ Acq - Admin		HR Approval: K. Fleming	Date: April 2023

#### JOB SUMMARY

Under the general direction of the Director of Transplant Quality and Compliance, this position is responsible for the organization, support, and facilitation of the UW Transplant Regulatory and Compliance program. This position plays a key role in ensuring on-going regulatory readiness and compliance with industry standards (i.e. OPTN, CMS, Joint Commission).

Extensive knowledge of clinical operations with a transplant program and the corresponding governing bodies, regulations, and bylaws are crucial to the success of the incumbent in this position. The incumbent evaluates, monitors, surveys, and analyzes individual transplant programs for regulatory compliance. This is performed by direct observation, discussion, and review of documents within the patient care setting and in an office environment. Additionally, the incumbent is directly responsible for advising UW Transplant leadership and staff regarding the regulatory environment through collaboration and operationalizing all aspects of the Organ Procurement and Transplantation Network (OPTN), Center for Medicare and Medicaid Services (CMS), and Joint Commission (JC) regulatory requirements. A high degree of knowledge in identifying, developing, and educating multidisciplinary and multilevel stakeholders regarding best practices at UW Transplant and Mechanical Circulatory Support Device (MCS) programs through the review of published research, nationally recognized transplant communications and organizations is essential.

A high degree of initiative and self-direction, organization, analysis, interpretation of policies, critical thinking, problem-solving, performance improvement, and healthcare regulatory experience is necessary for this position. The incumbent works primarily independently with general supervision from the Director of Transplant Quality and Compliance for evaluation of on-going work, initial direction regarding new initiatives and policies, and feedback on individual performance. This person works closely with a variety of internal and external stakeholders at all levels from leadership to frontline staff. Excellent verbal and written communication skills are critical in conveying education and information regarding policy changes and regulatory updates to stakeholders is required.

Strong leadership skills will contribute to the success of the incumbent in this role. This role has direct oversight of 5 RN positions in the role of organ allocation specialists. Direct knowledge of organ allocation including general allocation processes, regulations, and the roles of OAS team members within those processes is required.

#### MAJOR RESPONSIBILITIES

##### Regulatory Compliance and Oversight

- Coordinates and facilitates regular meetings with UW Transplant leadership as the internal pacing function to track and organize all regulatory related activity
- Analyzes current practices, policies, guidelines, and process compared to regulations and creates gap analyses to identify areas of noncompliance or at risk for non-compliance
- Leads the coordination and preparation for all requests for survey activity of the UW Transplant, including mock surveys and on-site surveys and desk audits within the transplant program, inpatient units, and peri-operative space as applicable
- Responsible for continuous monitoring of the external landscape with regards to policy changes and proposals and prepares policy briefings and/or recommendations to UW Transplant leadership; attends OPTN regional and other meetings as appropriate
- Coordinates the organizational response, in collaboration with UW Transplant leadership, for any survey follow-up requests, including the preparation of a written corrective action plan and/or submission of requested documentation
- Maintains appropriate documentation of all survey and regulatory related activity

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- Ensures regular maintenance to keep written policies and procedures reflective of current regulations and UW Transplant processes
- Administrator for the online policy management platform including ongoing review of policies, authoring and/or editing policies, policy approvals and policy publication
- UNet database administrator which duties include group development and monitoring, obtaining access, access removals, yearly access audits and reports
- Regularly communicates policy and procedure changes to UW Transplant staff; develops and/or implements ongoing training and education for transplant staff, fellows, physicians, and other personnel as applicable
- Collaborates with UW Quality, Safety and Innovation regulatory compliance coordinators to ensure alignment with organization-wide regulatory activity and communicate the status of UW Transplant regulatory activity to hospital leadership
- Routine chart audits of the ABO verification process in the operating room and the vessel storage operations in the blood bank

### Performance Improvement

- Collaborates with Transplant Quality Assessment and Performance Improvement (QAPI) program leadership, organ specific leadership, and UW Health process improvement teams/leadership to ensure regulatory compliance
- Participates in occurrence reporting of the UW Transplant program and the OPTN Patient Safety Net (PSN), educating staff as appropriate about event reporting as it pertains to patient safety, regulatory compliance, and other areas as identified
- Participation, development, and delivery of internal reports for UW Transplant leadership identifying key areas of compliance concerns and/or changes required
- Supports and/or facilitates performance improvement projects with multi-disciplinary teams to achieve improved patient and system outcomes and regulatory compliance
- Uses retrievable data (internal or external benchmarks) to identify vulnerable processes at risk of regulatory non-compliance to guide root cause identification and support improvement ideas
- Assures all regulatory and compliance documentation is complete and organized.
- Communicates updates to stakeholders as appropriate.

### Professional Development

- Represents the UW Transplant programs at internal and external meetings, as identified
- Keeps knowledge current of trends in the organ donation and transplantation industry through active participation and/or attendance in webinars, committees, list serves, seminars, as identified.
- Assumes personal responsibility for identifying own learning needs, development goals, and appropriately seeks guidance from mentors for support and coaching.

### Direct Reports

- Ensure appropriate staffing models and responsible for hiring, onboarding, and ongoing supervision of organ

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allocation specialists (OAS) including annual reviews

- Provide ongoing leadership and direction to the OAS team
- Ongoing evaluation and assessment of workflows to ensure efficiency and productivity
- Develop annual operating and capital budgets. Monitor budgets and authorize expenditures to remain in compliance with allocated financial resources. Prepare budget analysis with variance reports as required.
- Responsible for all HR related activity as it pertains to the OAS team

**ALL DUTIES AND REQUIREMENTS MUST BE PERFORMED CONSISTENT WITH THE UW HEALTH PERFORMANCE STANDARDS.**

### JOB REQUIREMENTS

Education	Minimum	Bachelor's degree in nursing
	Preferred	Master's degree from an accredited college or university in a healthcare related field
Work Experience	Minimum	5 years in transplant/healthcare, transplant/healthcare operations, quality/regulatory experience or a combination thereof
	Preferred	3 years' experience in leadership in an organ procurement organization, transplant center or associated healthcare environment
Licenses & Certifications	Minimum	Licensed as a Registered Nurse (RN) in the State of WI or holds a license issued by a jurisdiction that has adopted the nurse licensure compact
	Preferred	Certified Professional in Healthcare Quality (CPHQ), American Society for Quality (ASQ), Certified Quality Auditor (CQA), Regulatory Affairs Certification (RAC)
Required Skills, Knowledge, and Abilities		<ul style="list-style-type: none"> <li>• Extensive experience within a transplant center, organ procurement organization, or an associated healthcare environment</li> <li>• Effective organizational, planning, controlling, scheduling and project management abilities.</li> <li>• Effective leadership skills including strategic thinking, planning and problem solving.</li> <li>• Effective Human Relations skills including promote teamwork, create alliances, ensure a high level of employee, patient, visitor and external stockholder satisfaction.</li> <li>• Effective written and verbal communication skills</li> <li>• Effective skills in the development and delivery of educational inservices</li> <li>• Effective organizational, planning, controlling, scheduling and project management abilities.</li> <li>• Effective leadership skills including strategic thinking, planning and problem solving.</li> <li>• Effective Human Relations skills including promote teamwork, create alliances, ensure a high level of employee, patient, visitor and external stockholder satisfaction.</li> <li>• Effective analytic skills to analyze regulations, recommend policy changes and operationalize improved workflows.</li> <li>• Strong computer skills.</li> <li>• Extensive knowledge of healthcare regulations with ability to translate regulations into effective strategies to assure compliance.</li> <li>• Ability to respond and adapt to an ever-changing environment.</li> <li>• Strong organizational and project management skills.</li> <li>• Strong interpersonal skills to include the ability to facilitate, mentor, negotiate, and work collaboratively with others</li> <li>• Ability to function independently and manage multiple projects simultaneously.</li> <li>• Detail-oriented with the ability to effectively summarize and communicate</li> </ul>

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	complex regulatory documents		
<b>AGE SPECIFIC COMPETENCY (Clinical jobs only)</b>			
Identify age-specific competencies for direct and indirect patient care providers who regularly assess, manage and treat patients.			
<b>Instructions:</b> Indicate the age groups of patients served either by direct or indirect patient care by checking the appropriate boxes below. Next,			
<b>X</b>	Infants (Birth – 11 months)	<b>X</b>	Adolescent (13 – 19 years)
<b>X</b>	Toddlers (1 – 3 years)	<b>X</b>	Young Adult (20 – 40 years)
<b>X</b>	Preschool (4 – 5 years)	<b>X</b>	Middle Adult (41 – 65 years)
<b>X</b>	School Age (6 – 12 years)	<b>X</b>	Older Adult (Over 65 years)
<b>JOB FUNCTIONS</b>			
Review the employee's job description and identify each essential function that is performed differently based on the age group of the patient.			
<b>PHYSICAL REQUIREMENTS</b>			
<b>Indicate the appropriate physical requirements of this job in the course of a shift.</b> <i>Note: reasonable accommodations may be made available for individuals with disabilities to perform the essential functions of this position.</i>			
<b>Physical Demand Level</b>		<b>Occasional</b> Up to 33% of the time	<b>Frequent</b> 34%-66% of the time
		<b>Constant</b> 67%-100% of the time	
<b>x</b>	<b>Sedentary:</b> Ability to lift up to 10 pounds maximum and occasionally lifting and/or carrying such articles as dockets, ledgers and small tools. Although a sedentary job is defined as one, which involves sitting, a certain amount of walking and standing is often necessary in carrying out job duties. Jobs are sedentary if walking and standing are required only occasionally and other sedentary criteria are met.	<b>Up to 10#</b>	<b>Negligible</b>
	<b>Light:</b> Ability to lift up to 20 pounds maximum with frequent lifting and/or carrying of objects weighing up to 10 pounds. Even though the weight lifted may only be a negligible amount, a job is in this category when it requires walking or standing to a significant degree.	<b>Up to 20#</b>	<b>Up to 10#</b> or requires significant walking or standing, or requires pushing/pulling of arm/leg controls
	<b>Medium:</b> Ability to lift up to 50 pounds maximum with frequent lifting/and or carrying objects weighing up to 25 pounds.	<b>20-50#</b>	<b>10-25#</b>
	<b>Heavy:</b> Ability to lift up to 100 pounds maximum with frequent lifting and/or carrying objects weighing up to 50 pounds.	<b>50-100#</b>	<b>25-50#</b>
	<b>Very Heavy:</b> Ability to lift over 100 pounds with frequent lifting and/or carrying objects weighing over 50 pounds.	<b>Over 100#</b>	<b>Over 50#</b>
List any other physical requirements or bona fide occupational qualifications:			

Note: The purpose of this document is to describe the general nature and level of work performed by personnel so classified; it is not intended to serve as an inclusive list of all responsibilities associated with this position.