# New Business / Service Compliance Checklist

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| Facility: |  | New Business/Service Line: |  |
| Target Opening/Start Date: |  | Has the Compliance Officer been notified? |  | Yes |  | No |

| **Element** | **Resources** | **Action Required** | **Comments** | **Date Complete** |
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| **Regulatory** |
| Have Federal and State requirements (including program licensing) been assessed/reviewed for this program/service? | Policy on Licensing, Certification and Accreditation |  |  |  |
| Have Joint Commission requirements been assessed/reviewed for this program/service (if applicable)? |  |  |  |  |
| Are Policies and Procedures required for Joint Commission or State Requirements completed & approved? |  |  |  |  |
| Are any notifications required to CMS (Medicare/Medicaid) or state department of public health prior to startup of program/service? |  |  |  |  |
| Has business license been obtained (if required)? |  |  |  |  |
| Have physical plant requirements been met? |  |  |  |  |
| Have the CMS Physician Supervision requirements for provider-based diagnostic and therapeutic services been evaluated and put in place as required? |  |  |  |  |
| Is this a “Provider-Based” entity? |  | If yes, complete the applicable checklists.  |  |  |
| Medical Staff |
| Is the physician or advanced care practitioner (ACP) credentialed to provide the services in this new service line? |  |  |  |  |
| Has the scope of practice for all advanced care practitioner (ACP) been reviewed to ensure they are licensed to provide this service(s)? | [American Association of Nurse Practitioners](http://www.aanp.org/)http://www.aanp.org/ |  |  |  |
| Have the anticipated ordering/referring physicians been verified in PECOS? | [Medicare Provider Ordering and Referring Report](http://www.cms.gov/MedicareProviderSupEnroll/06_MedicareOrderingandReferring.asp)http://www.cms.gov/MedicareProviderSupEnroll/06\_MedicareOrderingandReferring.asp |  |  |  |
| Have state physician supervision requirements been met? |  |  |  |  |
| Are physicians on this medical staff engaged in Human Subject Research? |  |  |  |  |
| Joint Ventures |
| Is the program/service a Joint Venture? | Recommended Resources: * JV Policy and Procedure
* JV Guidelines and Requirements for JV arrangements
* Joint Venture Assessment Questionnaire
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| Legal / Contracting |
| Has Legal been notified of new service line development? |  |  |  |  |
| Does the Medical Director contract meet all requirements as stated in the organization’s Physician Transaction policy? |  Policy on Physician Transactions |  |  |  |
| Has Managed Care reviewed all contracts as needed? |  |  |  |  |
| Has Legal reviewed all contracts for services including physicians, vendors, third party billing companies, and any other contracted services? |  |  |  |  |
| If leasing office space to a physician, have the real estate leases been reviewed by Legal and/or Real Estate department to ensure compliance with applicable policy and to ensure that current Fair Market Value (FMV) has been assessed and documented? |  |  |  |  |
| Is the service/program/business owned in part or in whole by a physician? |  |  |  |  |
| Has legal reviewed all contracts for research services including physicians, research sponsors and/or contract research organizations?  |  |  |  |  |
| Documentation / Medical Records |
| Does the system for storage and retrieval of medical records ensure records are available for audit and medical record requests by payers? | Policy on Record RetentionPolicy on the Designated Record Set (or Legal Record) |  |  |  |
| Does the electronic billing system allow for adequate back-up and data retrieval to ensure compliance with Record Retention policy?  | Policy on Record RetentionPolicy on disaster recovery.  |  |  |  |
| If using an EMR for professional services, have the documentation templates been reviewed to ensure E&M documentation guidelines will be met? | Documentation Guidelines for E&M Serviceshttps://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/EMDOC.html |  |  |  |
| Professional Claim Billing/Coding |
| What type of professional providers will be performed in this location? (Physician, Mid-level (NP, PA, CNS, etc.) |  |  |  |  |
| Have the individual professional providers obtained their National Provider Identifiers (NPI's)?  |  |  |  |  |
| Have the individual professional providers NPI been validated and confirmed to be correct for their assignment of the CMS Specialty Code in billing system? |  |  |  |  |
| If one or more of the performing providers is advanced care practitioner (ACP), what name and NPI will appear on the CMS1500 claim form for each payer type? |  Policy on “Incident to” Services |  |  |  |
| If the Non Physician Practitioner is employed by the hospital, please contact your Compliance officer.  |  |  |  |  |
| Have CPT/HCPCS codes and documentation requirements been identified and reviewed by a Coding Compliance Manager? |  |  |  |  |
| Have encounter forms been created / updated and reviewed by a Coding Compliance Manager?  |  |  |  |  |
| Do non-Medicare payers have specific coding / reimbursement requirements? If so, have these requirements been documented as outlined facility policy? | Policy on Payer Specific Coding Instructions |  |  |  |
| Have there been defined processes for the charge capture and billing? |  |  |  |  |
| Has the practice management system been updated to include the new CPT codes and fees? |  |  |  |  |
| Has the professional billing function been assigned to an Internal process or to a 3rd party Billing company? |  |  |  |  |
| If the billing has been assigned to a 3rd Party Billing Company is there a contract in place to support the billing to be performed for this new Service Line? |  |  |  |  |
| Has the 3rd party billing company contract, processes, policies, etc. been reviewed by Legal and/or Compliance to ensure all CMS requirements have been met? |  |  |  |  |
| Has the Compliance Training been scheduled/assigned to ensure the 3rd Party Billing company receives Compliance training and applicable reference material? |  |  |  |  |
| Does the new service/business meet the Medicare/Medicaid program requirements for billing including review of applicable LCD’s/NCD’s and/or CMS transmittals? |  |  |  |  |
| Have any New Provider Audits and New Provider Orientations been arranged? |  |  |  |  |
| Are physicians billing for research related services? |  |  |  |  |
| Facility Charging / Coding / Billing |
| Have you reviewed the charging, coding and billing and documentation forms, policies and practices with a Coding Compliance Manager? | Policy on Coding Compliance |  |  |  |
| Who will be responsible for the assignment of ICD-10 diagnosis codes? Is this person properly educated, qualified and competency tested? | Policy on Continuing Education Requirements for Coding Staff |  |  |  |
| Has a 60-90 day (post program start up) compliance audit of coding, charging and documentation been scheduled to ensure errors/problems are identified and corrected early in the startup phase of the service? |   |  |  |  |
| Who will validate CPT/HCPCS codes against the clinical documentation? |  |  |  |  |
| Have all items on CDM been reviewed and audited for accuracy of codes, descriptions, and to ensure that any unique CMS (Medicare/Medicaid) requirements have been met? |  |  |  |  |
| Has CDM’s been tested to ensure the appropriate charge description and associated charges appear correctly on the claim/patient’s bill? |  |  |  |  |
| Has a charge reconciliation process been implemented? |  |  |  |  |
| Is there a process in place for the billing staff to return claims that were incorrect on initial submission to the hospital for correction?  | Policy related to Rebilling Claims identified through the coding compliance audits process. Policy related to Voluntary Refunds/Re-Bills |  |  |  |
| If a 3rd party billing service is to be utilized, has this been reviewed by Compliance to ensure all CMS (Medicare/Medicaid) requirements have been met? |  |  |  |  |
| Have the EHR and documents utilized to input charges been reviewed for accuracy and to ensure all CMS (Medicare / Medicaid) requirements have been met?  |  |  |  |  |
| Has the denial management plan been reviewed to ensure any charging/billing errors are identified and corrected? |  |  |  |  |
| Has the cancel / credit tracking system been reviewed to ensure that all overpayments will be identified and promptly returned to the payer? |  |  |  |  |
| Has a process been implemented to ensure that any outpatient charges related to the acute hospitalization are identified and meet the requirements of the 3‑day rule?  | Policy on the Three Day Window |  |  |  |
| Has process been implemented to ensure that ABN’s (Advanced Beneficiary Notice), MSP (Medicare Secondary Payer) and CMS Conditions of Admission/Participation are properly utilized? | Policy on Medicare Secondary Payer ScreeningPolicy on Advanced Beneficiary NoticesCMS Conditions of Participationhttps://www.cms.gov/CFCsAndCoPs/ |  |  |  |
| Are E&M leveling criteria established for facility charge capture and associated policies and procedures completed? |  |  |  |  |
| Are encounter form/charge form policies and procedures completed? |  |  |  |  |
| Does the new service/business meet the Medicare/Medicaid program requirements for billing including review of applicable LCD’s / NCD’s and/or CMS transmittals? | CMS Transmittalshttps://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/index.html |  |  |  |
| Has a Medicare Coverage Analysis and/or research billing plan been completed for all clinical trials actively enrolling patients?  | Policy on Clinical Trial Billing |  |  |  |
| Leadership |
| Have Service Line / Business leaders attended (or enrolled in) Physician Transaction Training? |  |  |  |  |
| HIPAA / Privacy Compliance  |
| Has the new business service been added to the HIPAA organization chart and/or Joint Notice of Privacy Practices list? |  |  |  |  |
| What applications containing Protected Health Information (PHI) are involved? |  |  |  |  |
| If access, use or disclosure of facility data is involved has a security risk assessment been completed for those applications?  |  |  |  |  |
| Are there processes in place for auditing access for appropriateness? |  |  |  |  |
| Is staff educated as to reporting privacy / compliance incidents? |  |  |  |  |
| Are there Business Associates / Contracted vendors involved in the new service?  If so, who? | Policy on Business Associates |  |  |  |
| Does the new service require the posting of a Notice of Privacy Practices (NPP) and does staff have a process for presenting the NPP to patients? | Policy on Notice of Privacy Practices |  |  |  |
| Has the Compliance or Privacy Officer completed a Walk-through? | Walk-Through Checklist |  |  |  |
| If access, use or disclosure of data for research purposes is involved, is this access approved by written HIPAA authorization or IRB waiver of authorization per policy? |  |  |  |  |
| Supply Chain Management (SCM) |
| Has SCM been notified to evaluate the need for supply account set-up? |  |  |  |  |
| Has SCM been notified if plan to utilize 340B purchasing program? |  |  |  |  |
| Pharmacy / Medications |
| Has Pharmacy Services been notified if plan to utilize 340B purchasing program? | Policy on 340B Compliance |  |  |  |
| Has the Pharmacy Director been notified if medications, to include controlled substances, are present in this setting? |  |  |  |  |
| **Other Elements: To be Determined by the Evaluator** |
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