

# **Independent Healthcare Regulation**

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**Annual Return Guidance for Providers**

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## Background

Following the successful registration of independent healthcare services, we request that providers regularly submit important information to help make sure our inspection process is intelligence-led, targeted, outcome-focused, and efficient.

In December each year, we email all registered services to request the completion of an annual return for the year (January to December). The annual return requests essential information about the service and its provider, such as its composition, activities, incidents and accidents and staffing details.

Either the hospital or clinic annual return should be completed on the eForms portal. The deadline for completing and submitting the annual return is early February.

## How to submit an annual return

If you have not completed an annual return before, please see our Portal User Guide on the [HIS website](#).

As you are completing your annual return, please look at your registration certificate that will include the provider and service details and conditions of registration.

If details are incorrect, please submit the correct notification to us so we can update your details. [Please refer to the IHC - Notification Guidance for Providers](#)

The basic steps to completing an annual return are:

- log into HIS portal [Quality Assurance Dashboard \(scot.nhs.uk\)](https://scot.nhs.uk)
- scroll down to annual returns
- select '+ Create new annual return form'
- select New annual return (clinics or hospitals)
- complete all the questions. If there are any questions that are not applicable to your service, please mark this as N/A. However, if we believe that it is a question you should have answered, we will ask you to amend this accordingly when we review your annual return submission.
- If you are unable to view all the questions, please zoom out in your browser.
- the annual return can be saved and returned to at a later date
- submit annual return – click the submit button at the bottom right-hand side of screen

## How to complete an annual return

The annual return will ask you a series of questions, under different sections. The below guide will help you answer the questions correctly.

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## Provider Details

Please provide details of the provider. Do not confuse the provider with the service. Service details should be completed in the section below **2 – Service details**.

The provider is either:

- the name of the self-employed person working as a sole trader (if you registered with HIS as an individual) or,
- the name of the:
  - company
  - partnership
  - registered charity
  - limited liability partnership
  - corporate body
  - unincorporated body.

If your provider is a company that is registered with Companies House, your details **must match the information** recorded on the [Companies House website](#). This will include the provider's name, the registered address of the provider and the relevant individuals. A relevant individual is:

- a director, manager, or secretary of the body corporate (where the applicant is a body corporate other than a local authority)
- a partner in the firm (where the applicant is a partnership)
- a member of the firm (where the applicant is a limited liability partnership)
- a member of the firm (where the applicant is a limited partnership), or who are
- concerned in the management or control of the association (where the applicant is an unincorporated association other than a firm).

If details do not match, you **must** submit the correct notification to us so we can update our database and online register and send you a new HIS registration certificate. Please refer to the [IHC - Notification Guidance for Providers](#).

## Service Details

Please provide details of the service. The service is your trading name, and the service address is the place that your service is provided from.

We ask you to confirm what treatments and procedures you offer. Please tick all that are relevant. Please note the dentistry procedures are at the bottom of the list. You should only be offering treatments and procedures that are allowed within your conditions of registration, as listed on your HIS registration certificate. Please confirm if you work from either:

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- fixed premises (such as a hospital/clinic located within a commercial building or residential home)
- service user’s own homes (mobile),
- online.

If details do not match, please submit the correct notification to us so we can update your details. Please refer to the [IHC Notification Guidance for Providers](#).

We will also ask you for expiry dates for your insurance policies.

## Invoice Details

We will ask you to confirm what address your annual continuation fee should be sent to.

Please provide the email address and the postal address where you would like your annual continuation fee invoice to be sent. It should either be your:

- service address
- provider address
- other (such as your headquarters / accounts payable departments).

We will ask you to confirm your annual continuation fee category. The current categories are:

- Hospitals
- Clinics carrying out surgical procedures
- Clinics carrying out weight loss using controlled drugs and online primary care services
- Clinics carrying out non-surgical procedures (with staff, including practicing privileges, additional directors, admin staff)
- Clinics carrying out non-surgical procedures (only one individual / single-handed practitioner) \*
- Clinics providing dental services (including dental hygiene services).

\* The category of **‘Clinics carrying out non-surgical procedures (only one individual / single-handed practitioner)’** is only available to a service where there is **only one person** involved. If the service has a prescriber/administrator/granted practicing privileges/staff/directors on Companies House, in addition to the one practitioner, this would be classified as ‘staff’.

Annual return for Hospital’s - We will ask you to confirm the total number of beds/places available in your service stated on the service's certificate of registration. If details do not match, you **must** submit the correct notification to us so we can update our database and online

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register and send you a new HIS registration certificate. Please refer to the [IHC Notification Guidance for Providers](#).

Further information on our [regulatory fees can be found on our website](#).

## Service User Details (Clinic annual returns only)

Please provide us with the total number of service users seen in the last year (January to December) and the number of treatments.

## Admission and Discharge (Hospital annual returns only)

We will ask you to provide the total number of beds/places in the service as of the end of the last calendar year and if this matches the certificate of registration. If not, you must submit the notification 'Application to vary, remove or add conditions of registration'. Please refer to the [IHC - Notification Guidance for Providers](#).

We will ask you to provide the total number of outpatient appointments, admissions (including day case and discharges (including unplanned) in the last calendar year.

We will also ask you to provide the:

- total number of deaths
- total number of unexpected deaths
- total number of expected deaths related to end of life care, and
- how many of the expected deaths were referred to the Procurator Fiscal in the last calendar year.

If any unexpected deaths occur, these must be reported by submitting the notification 'Unexpected death of a service user'. Please refer to the [IHC - Notification Guidance for Providers](#).

## Resuscitation (Hospital annual returns only)

We will ask you to confirm that there is a resuscitation care plan in place for each person receiving care and there is a procedure in place for managing rapid clinical deterioration.

We will ask if the resuscitation equipment is on site and how often the resuscitation equipment checked.

## Protection of Vulnerable Groups

We will ask you to confirm if your service has a policy in place for:

- Adult support and protection
- Child protection.

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All services must have an adult support and protection policy in place. Services that have patients under the age of 18 or work with families must have a child protection policy in place.

Clinic annual return only - If you provide a service from a premises where other people live, all persons aged 16 and above must have a basic disclosure check. It is the responsibility of the service to request/undertake this check. The practitioner will still require an enhanced PVG. Further [guidance on background checks can be found on our website](#).

Hospital annual return only – For the patients under the age of 18, is there a system in place to contact the ‘Named Person’ for the child/young adult’.

## Staffing Details

Please provide us with the information on the staff that work in your service. The definition of staff includes those employed and those granted practising privileges. This also includes clinical and non-clinical staff.

All services that recruit staff must have a recruitment policy in place.

All services that grant practicing privileges must have a practicing privileges policy and contracts in place. Further [guidance on practicing privileges is available on our website](#) along with a practicing privileges checklist for clinics.

If your staffing levels change, which will affect which continuation fee category you are listed under, please submit the change to staffing level notification. Please refer to the [IHC - Notification Guidance for Providers](#). The IHC fee categories are included in the [Fee information booklet](#).

## Third Party Accreditation

Please provide us with the information on any accreditation programmes, including:

- External accreditation programmes
- Clinical pathology accreditation
- Clinical radiology accreditation
- Accreditation for in-house decontamination and sterilisation.

We will ask you for expiry dates for any accreditations.

We will ask you to confirm if the service:

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- uses dental radiography
- uses nuclear medicine
- uses radiotherapy
- uses diagnostic radiology, including computed tomography, interventional radiology, fluoroscopy, mammography
- uses 3B or 4 lasers or intense pulsed light (IPL).

## Pharmacy and Medicine

Providers are responsible for ensuring that they comply with legal requirements and follow current best practice and guideline recommendations with regard to the safe, effective, and secure use of medicines. A [medicines governance tool is available for services to use on our website](#).

Please provide us with the information on medicines that are used in your service. Medicines include:

- Prescription only medicine
- Emergency medicines (such as adrenaline, hydrocortisone, chlorpheniramine)
- Controlled drugs (see below table)

Examples of Controlled Drugs include:	
Schedule 2	alfentanil, diamorphine, fentanyl, ketamine, methylphenidate, morphine, oxycodone
Schedule 3	buprenorphine, diethylpropion, midazolam, phentermine, temazepam, tramadol, gabapentin, pregabalin
Schedule 4	benzodiazepines, zolpidem, zopiclone
Schedule 5	co-codamol, codeine linctus, dihydrocodeine (oral)

All services that use medicines must have a comprehensive medicine management system in place including policies and records for processes such as procurement, storage, prescription, administration, and destruction.

If your service uses **prescription only medicines**, we will ask you to provide details of the prescribers. If any drug errors or near misses occur, these must be reported as a drug error notification. Please refer to the [IHC - Notification Guidance for Providers](#).

### Controlled drugs

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If your service uses controlled drugs, you must comply with legal requirements and follow good practice guidelines with regard to the safe and secure handling of controlled drugs.

All services that use controlled drugs should appoint a clinical lead/controlled drugs accountable officer who takes responsibility for the safe and secure handling of controlled drugs in the service. It is the responsibility of the service to contact the Home Office to confirm whether or not a Home Office Licence is required.

If you have introduced controlled drugs in your service since registration, please complete the introduction of controlled drugs notification. Please refer to the [IHC - Notification Guidance for Providers](#)

If any controlled drug incidents occurred in the service during the last calendar year, these should be reported as a controlled drug incident notification. Please refer to the [IHC - Notification Guidance for Providers](#).

### **Prescribers**

We will ask you to confirm if the prescriber provides prescribing services for other HIS registered services and also services or individuals not registered with Healthcare Improvement Scotland. (including non-healthcare professionals).

## **Financial Management (Hospital annual returns only)**

We will ask you to confirm if your service manages patient's funds and how the service manage accounts of patients and there is a clear financial record.

## **Infection Prevention and Control**

We will ask you to confirm that your service has a policy in place for Infection prevention and control.

Services should insure that their policy is aligned to the guidance in the [HIS Infection prevention and control standards 2022](#) and [National Infection Prevention and Control Manual 2022](#).

## **Quality Improvement**

We will ask you if you service has a quality improvement plan. Services should develop quality improvements plans which include areas for improvement highlighted from audits, complaint investigations or your inspections. Quality improvement plans should have associated action plans detailing any improvements implemented or planned.

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## Incidents and Accidents

We will also ask you for details on any serious injuries, serious complications, accidents, and incidents that have occurred in your service over the last year (January to December).

Services should be aware of specific notifications that they are required to submit to HIS via the eForms portal relating to serious injuries, serious complications, accidents, and incidents. Please refer to the [IHC - Notification Guidance for Providers](#).

## Complaints

We will ask you to confirm that your service has a policy in place for complaints.

All services should have a complaints policy and should have information available to their patients about their complaints policy. The policy should include a statement that your patients can complain to HIS about your service at any time, along with our contact details.

## Duty of Candour

We will ask you to confirm that your service has a policy in place for Duty of Candour.

All services should have a Duty of Candour policy, publish annual reports, and ensure staff are trained in the duty of candour principles. Further information can be found in the [IHC Duty of Candour Template for Providers on our website](#).

## Contingency Planning

We will ask you to confirm that your service has a contingency plan in place in the event that the service has to close.

## Waste Management

We will ask you to confirm that your service has:

- A policy in place for waste management.
- A contract in place for waste management.

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